GE Healthcare

DINAMAP™ ProCare Monitor
Service Manual

DINAMAP ProCare Monitor
English
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GUARANTEE

All equipment sold by GE Medical Systems *Information Technologies*, is fully guaranteed as to materials and workmanship for a specified period. Refer to your warranty for more information. GE Medical Systems *Information Technologies* reserves the right to perform guarantee service operations in its own factory, at an authorized repair station, or in the customer's installation.

Our obligation under this guarantee is limited to repairing, or, at our option, replacing any defective parts of our equipment, except fuses or batteries, without charge, if such defects occur in normal service.

Claims for damage in shipment should be filed promptly with the transportation company. All correspondence covering the instrument should specify the model and serial numbers.

GE MEDICAL SYSTEMS *Information Technologies*
A GE Healthcare Company

NOTE: In addition to software version RAI, the information in this manual also applies to earlier DINAMAP® ProCare Monitor software versions. There are no user-apparent differences among these software versions. Due to continuing product innovation, specifications in this manual are subject to change without notice.

GE Medical Systems *Information Technologies* will make available on request such circuit diagrams, component diagrams, component parts lists, descriptions, calibration instructions, or other information which will assist the users or appropriately qualified technical personnel to repair those parts of the equipment which are classified by GE Medical Systems *Information Technologies* as repairable.

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CAUTION: In the United States of America, Federal Law restricts this device to sale by or on the order of a physician.

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1 Introduction

For your notes

Revision History

Each page of this manual has a revision letter located at the bottom of the page. This letter identifies the revision level of the entire manual. This may be important if you have different manuals and you do not know which is the most current.

For the initial release, all pages have the revision letter A. For the second update, all pages receive the revision letter B. The latest letter of the alphabet added to the table below corresponds to the most current revision.

Revision	Comment
A	Initial Release
B	Add EMC Compliance Testing Tables
C	Update specifications, tests, FRU drawings, FRU lists, format, and add error log feature information.
D	Update CE Mark Notified Body and equipment symbols.

Manual Purpose

This manual supplies technical information for service representatives and technical personnel so they can maintain the equipment to the assembly level. Use it as a guide for maintenance and electrical repairs considered field repairable. Where necessary the manual identifies additional sources of relevant information and technical assistance. See the operator's manual for the instructions necessary to operate the equipment safely in accordance with its function and intended use.

Ordering Manuals

A paper copy of this manual will be provided upon request. Contact your local GE representative and request the part number on the first page of the manual.

Safety Information

The information presented in this section is important for the safety of both the patient and operator. This chapter describes how the terms Danger, Warning, Caution, Important, and Note are used throughout the manual. In addition, standard equipment symbols are defined.

Responsibility of the Manufacturer

GE is responsible for the effects on safety, reliability, and performance only if:

- assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by GE;
- the electrical installation of the relevant room complies with the requirements of appropriate regulations; and
- the monitor is used in accordance with the instructions of use.

General

This device is intended for use under the direct supervision of a licensed health care practitioner.

This device is not intended for home use. Federal law restricts this device to be sold by or on the order of a physician.

Contact GE for information before connecting any devices to the equipment that are not recommended in this manual.

Parts and accessories used must meet the requirements of the applicable IEC/EN 60601 series safety standards, and/or the system configuration must meet the requirements of the IEC 60601-1-1 medical electrical systems standard.

Periodically, and whenever the integrity of the device is in doubt, test all functions.

The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- use of the accessory in the PATIENT VICINITY; and
- evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-1 harmonized national standard.

If the installation of the equipment, in the USA, will use 240V rather than 120V, the source must be a center-tapped, 240V, single-phase circuit.

References to Persons, Places, and Institutions

References to persons, places, and institutions used within this manual are solely intended to facilitate user comprehension of the ProCare Monitor Monitor's use and functions. Extreme care has been taken to use fictitious names and related information in the examples and illustrations provided herein. Any similarity of this data to persons either living or dead and to either current or previously existing medical institutions should be regarded as coincidental.

Warnings, Cautions, and Notes

The terms danger, warning, and caution are used throughout this manual to point out hazards and to designate a degree or level or seriousness. Familiarize yourself with their definitions and significance. Hazard is defined as a source of potential injury to a person.

DANGER indicates an imminent hazard which, if not avoided, will result in death or serious injury.

WARNING indicates a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury.

CAUTION indicates a potential hazard or unsafe practice which, if not avoided, could result in minor personal injury or product/property damage.

NOTE provides application tips or other useful information to assure that you get the most from your equipment.

Product Specific Hazards

Warnings

- Do not use the ProCare Monitor in the presence of magnetic resonance imaging (MRI) devices. There have been reports of sensors causing patient burns when operating in an MRI environment.
- Do not use the Monitor in the presence of flammable anesthetics.
- To help prevent unintended current return paths with the use of high frequency (HF) surgical equipment, ensure that the HF surgical neutral electrode is properly connected.
- To avoid personal injury, do not perform any servicing unless qualified to do so.
- WARNING: These Monitors should not be used on patients who are connected to cardiopulmonary bypass machines.
- If powering the Monitor from an external power adapter or converter, use only GE Medical Systems *Information Technologies*-approved power adapters and converters.
- The Monitor does not include any user-replaceable fuses. Refer servicing to qualified service personnel.
- To reduce the risk of electric shock, do not remove the cover or the back. Refer servicing to a qualified service person.
- If the accuracy of any determination reading is questionable, first check the patient's vital signs by alternate means and then check the ProCare Monitor for proper functioning.
- The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.

Cautions

- Do not use replacement batteries other than the type supplied with the Monitor. Replacement batteries are available from GE Medical Systems - *Accessories and Supplies*.

- The ProCare Monitor is designed to conform to Electromagnetic Compatibility (EMC) standard IEC 60601-1-2 and will operate accurately in conjunction with other medical equipment which also meets this requirement. To avoid interference problems affecting the Monitor, do not use the Monitor in the presence of equipment which does not conform to these specifications.
- Place the ProCare Monitor on a rigid, secure surface. Monitor must only be used with mounting hardware, poles, and stands recommended by GE Medical Systems *Information Technologies*.
- The weight of the accessory basket contents should not exceed 5 lb (2.7kg).
- Arrange the external AC/DC power converter, air hoses, and all cables carefully so they do not constitute a hazard.
- Verify calibration of BP parameter (temp and pulse oximeter do not require calibration). Ensure that the display is functioning properly before operating the ProCare Monitor.
- Do not immerse the Monitor in water. If the Monitor is splashed with water or becomes wet, wipe it immediately with a dry cloth.
- Do not gas sterilize or autoclave.
- Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.
- The equipment or system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.
- The ProCare Monitor, when used with GE Medical Systems Information Technologies-approved applied parts and accessories, is protected against defibrillator damage.

NOTE: The electromagnetic compatibility profile of the ProCare Monitor may change if accessories other than those specified for use with the ProCare Monitor are used.

Equipment Symbols

The following symbols are associated with the ProCare Monitor. Some of the symbols may not appear on all equipment.

NOTE: The model of the Monitor determines which symbols appear on it.

Attention, consult accompanying documents

Silence

Alarms

+ / -

Menu

Inflate/Stop

Cycle

History

Print

On/Off

Battery Power

External Communications Port Connector

Charging

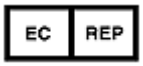
Defibrillator-proof type BF equipment

External AC or DC power indicator

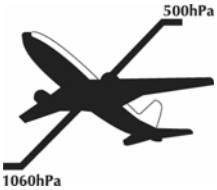
Class II equipment according to IEC 60536

Manufacturer: This symbol is accompanied by the name and the address of the manufacturer.

Manufacturing Date: This symbol is accompanied by the date of the manufacturing.



European authorized representative.



Packaging label depicting the transportation and storage atmospheric pressure range of 500 to 1060 hPa.

WASTE OF ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE): This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

IPX1

The DINAMAP® ProCare Monitor is protected against vertically falling drops of water and conforms with the IEC 529 standard at level of IPX1. Vertically falling drops shall have no harmful effects to the Monitor.

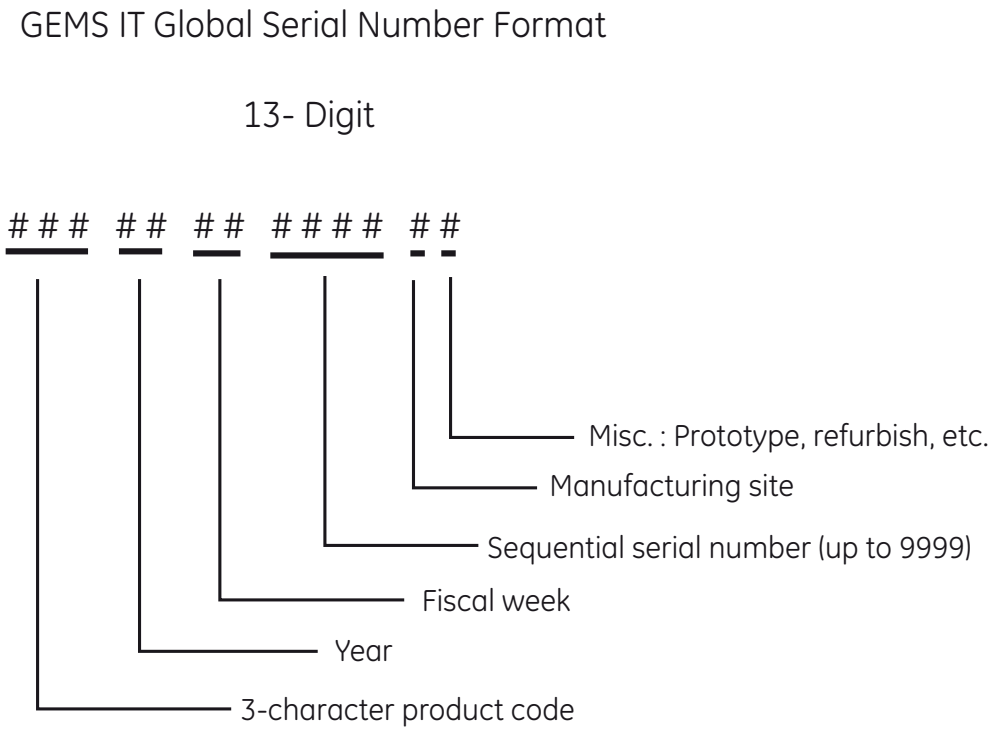
Service Requirements

Follow the service requirements listed below.

- Refer equipment servicing to GE Medical Systems *Information Technologies* authorized service personnel only.
- Any unauthorized attempt to repair equipment under warranty voids that warranty.
- It is the user's responsibility to report the need for service to GE Medical Systems *Information Technologies* or to one of GE's authorized agents.
- Failure on the part of the responsible individual, hospital or institution using this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.
- Regular maintenance, irrespective of usage, is essential to ensure that the equipment will always be functional when required.

Equipment ID

The following graphic illustrates the components of the monitor's serial number.



Intended Audience

This manual is intended for service representatives and technical personnel who maintain, troubleshoot, or repair this equipment.

Intended Use

General Use

- The ProCare Monitor is intended to monitor one patient at a time in a clinical setting.
- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- To ensure patient safety, use only parts and accessories manufactured or recommended by GE Medical Systems *Information Technologies*. Parts and accessories used shall meet the requirements of IEC 60601-1-1.
- Disposable devices are intended for single use only. They should not be reused.
- Periodically, and whenever the integrity of the monitor is in doubt, test all functions.

Related Manuals

Manual	Title
2009360-001	DINAMAP ProCare Operation Manual

Service Policy

The warranty for this product is enclosed with the product in the shipper carton. All repairs on products under warranty must be performed or approved by Product Service personnel. Unauthorized repairs will void the warranty. Only qualified electronics service personnel should repair products not covered by warranty.

Service Contracts

Extended warranties can be purchased on most products. Contact your Sales Representative for details and pricing.

Assistance

If the product fails to function properly, or if assistance, service or spare parts are required, contact Customer Support. Before contacting Customer Support, it is helpful to attempt to duplicate the problem and to check all accessories to

ensure that they are not the cause of the problem. If you are unable to resolve the problem after checking these items, contact GE Medical Systems *Information Technologies*. Prior to calling, please be prepared to provide:

- product name, model number, and serial number
- a complete description of the problem

If repair parts or service are necessary, you will also be asked to provide:

- the product serial number
- the facility's complete name, address, and account number
- a purchase order number if the product is to need of repair or when you order spare parts
- the facility's GE Medical Systems *Information Technologies* account number, if possible
- the appropriate part number for spare or replacement parts

Service

If your product requires warranty, extended warranty or non-warranty repair service, call Customer Support and a representative will assist you. To facilitate prompt service in cases where the product has external chassis or case damage, please advise the Customer Support representative when you call.

The Customer Support representative will record all necessary information and will provide you with a Return Merchandise Authorization Number (RMA). Prior to returning any product for repair, you must have a RMA number. Contact GE Medical Systems I*nformation Technologies* at **1-800-558-7044.**

Monday through Friday, 8:00 a.m. to 6:00 p.m. EST, excluding holidays.

Packing Instructions

Follow these recommended packing instructions.

- Remove all hoses, cables, sensors, and power cords from the monitor before packing.
- Pack only the accessories you are requested to return; place them in a separate bag and insert the bag and the product inside the shipping carton.
- Use the original shipping carton and packing materials, if available.

If the original shipping carton is not available:

- Place the product in a plastic bag and tie or tape the bag to prevent loose particles or materials from entering openings such as hose ports.
- Use a sturdy corrugated container to ship the product; tape securely to seal the container for shipping.
- Pack with 4 to 6 in. of padding on all sides of the product.

Insurance

Insurance is at the customer's discretion. The shipper must initiate claims for damage to the product.

Service No Charge Rental

A no charge rental unit is provided at no charge during the warranty period of the product when we perform the repair service.

- GE Medical Systems *Information Technologies* pays the shipping charges for a loaner sent to the customer for product repairs under the warranty.
- Rental units are available in non-warranty situations.
- The customer pays the shipping charges to return a rental.

All loaners provided to customers must be returned within the specified time stated on the loaner agreement or a rental fee will be incurred.

Repair Parts

Repair parts can be ordered from GE Medical Systems *Information Technologies:*

Via phone: 1-800-558-7044, or

Via FAX: 1-800-421-6841

Exchange replacement assemblies such as Circuit Board Assemblies also are available; ask the Customer Support representative for details.

Please allow one working day for confirmation of your order. All orders must include the following information.

- Facility's complete name, address, and phone number
- FAX number
- Your purchase order number
- Your GE Medical Systems *Information Technologies* account number

Disposal of Product Waste

As you use the ProCare Monitor, you will accumulate solid wastes that require proper disposal or recycling. These include batteries, patient applied parts, and packaging material.

Batteries

CAUTION
Do not incinerate batteries.

The sealed, rechargeable backup battery contains lead and can be recycled. The rechargeable memory battery is of the Sealed Lead Acid form. Discharge this battery prior to disposal. Place the battery in packaging which electrically isolates its contents. Do not puncture or place the battery in a trash compactor. Do not incinerate the battery or expose it to fire or high temperatures. Dispose in accordance with regional body controlled guideline.

Patient Applied Parts

Certain patient applied parts, such as those with adhesive (disposable SpO_2 sensors), are intended for single use and should be disposed of properly as medical waste in accordance with regional body controlled guideline.

Other patient applied parts, such as blood pressure cuffs, should be cleaned according to instructions. Inspect reusable applied parts for wear, replace as necessary, and dispose of used product as medical waste in accordance with regional body controlled guideline.

Packaging Material

Retain original packaging materials for future use in storing or shipping the Monitor and accessories. This recommendation includes corrugated shippers and inserts.

Whenever possible recycle the packaging of accessories and patient applied parts.

Monitor

At the end of its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of the product, please contact GE Medical Systems *Information Technologies* or its representatives.

2 Equipment Overview

For your notes

Equipment Description

The ProCare Monitor provides a small, portable, easy-to-use monitoring alternative for sub-acute hospital and non-hospital settings. The DC-operated Monitor offers noninvasive determination of systolic blood pressure, diastolic blood pressure, mean arterial pressure, pulse rate, oxygen saturation, and temperature. Monitors are available with or without integrated printers. ProCare Monitors are intended for use in various markets, from the physician's office to sub-acute triage and medical/surgical units.

All devices are tested and calibrated during manufacturing and are certified for operation at installation.

Indicators for external DC operation (from AC mains), battery operation, and battery charging are at the front of the unit.

At the time of publication, the available functioning parameters included the following:

- BP
- Nellcor® Pulse oximetry (SpO_2)
- Masimo® Pulse oximetry (SpO_2)
- Alaris® Oral and Rectal thermometry
- thermal recorder/printer

Other DINAMAP ProCare features include:

- the ability to use industry standard accessories
- remote alarm capability
- five single-function buttons for quick access to Alarm Silence, Record, Freeze, BP Start/Stop, and STAT BP

DINAMAP ProCare Monitors provide non-invasive determination of systolic blood pressure, diastolic blood pressure, mean arterial pressure, pulse rate, temperature, and oxygen saturation.

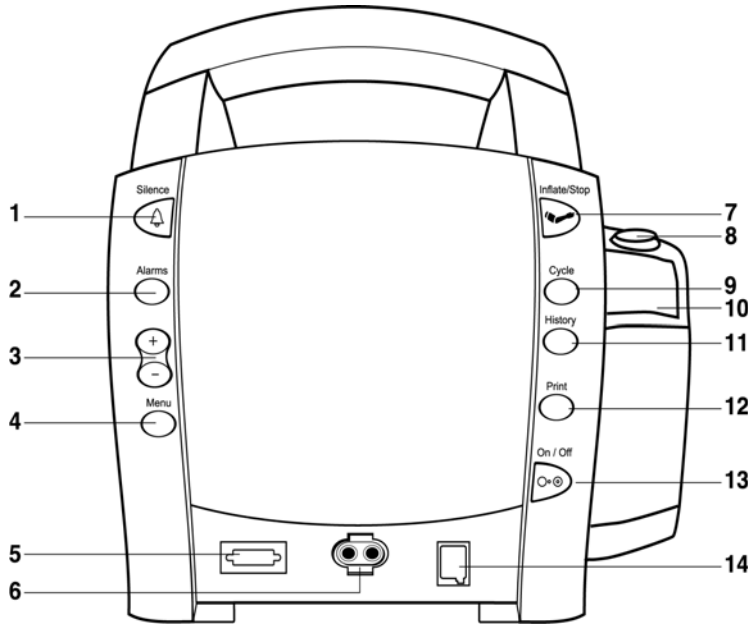
Product Configurations

Each ProCare Monitor is supplied with an accessory pack. The contents of the pack vary according to model. Unpack the items carefully, and check them against the checklists enclosed within the accessory boxes. If an accessory is missing or if an item is in a nonworking condition, contact GE Medical Systems *Information Technologies* Customer Service immediately.

It is recommended that all the packaging be retained, in case the ProCare Monitor must be returned for service in the future.

Basic Components

Front Panel Controls and Indicators

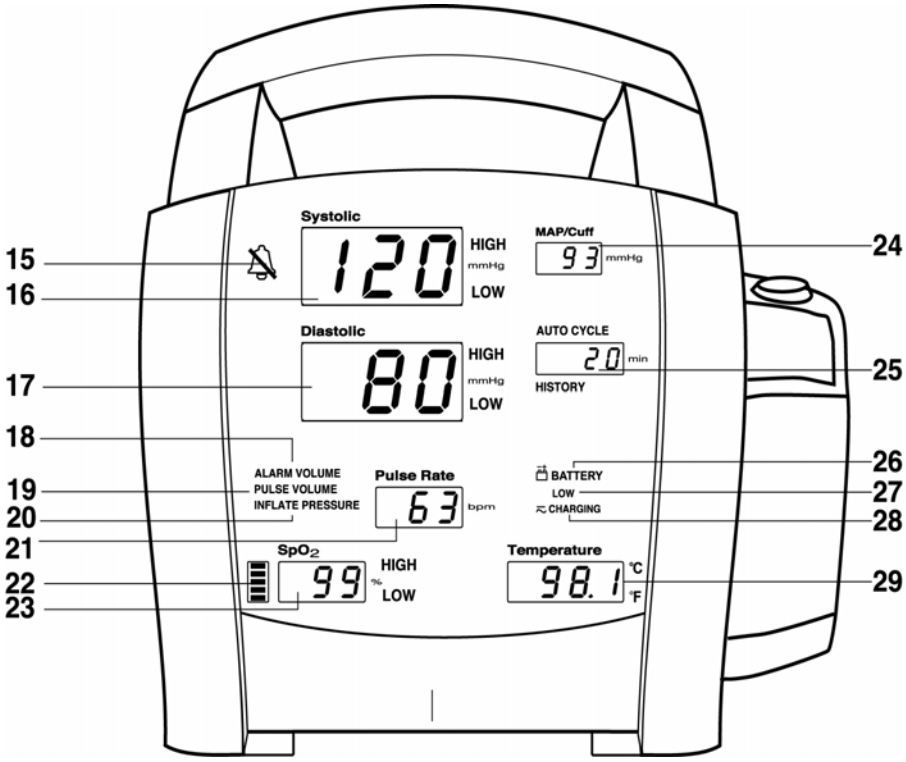


Buttons

1. Silence button: Press to mute audible alarms. Any alarm active that is acknowledgeable is also removed whenever this key is pressed. When pressed after alarm sounds (silence active), the silence icon (bell) lights to indicate that audible alarms have been silenced for 2 minutes.
2. Alarms button: Press to view or adjust parameter alarm settings.
3. +/- button (Plus/Minus): These buttons are active when the following user modes are active: limit, menu, cycle, and history. When limit or menu mode is active, pressing the **+** button increases an adjustable setting and the **-** button decreases an adjustable setting. When the cycle or history mode is active, pressing the +/- buttons displays the next or previous cycle selection or entry in the history list, respectively. When you reach the beginning or ending of a list, a key-click sounds.
4. Menu button: Press to access menu settings that can be adjusted while in clinical mode (i.e., **ALARM VOLUME, PULSE VOLUME, INFLATE PRESSURE;** refer to *Operating Modes* in this section for a description of clinical mode).
5. SpO_2 sensor connector: SpO_2 sensor extension cable attaches here.
6. BP connector: BP cuff hose attaches here.
7. Inflate/Stop button: Press to start a manual BP determination or stop any BP determination.
8. Temperature probe holster: Temperature probe is stored here.
9. Cycle button: Press to start Auto Cycle or STAT mode.

10. Temperature probe cover storage: Box of probe covers is stored here.
11. History button: Press to activate the History mode to view stored patient data. The most recent entries are displayed first. Press and hold the button for 2 seconds to clear all entries stored. Refer to the *History* section of this manual for more information.
12. Print button: Press to print currently displayed values or all stored entries when in history mode.
13. On/Off button: Controls on/off state of monitor; push for power on and push again for power off.
14. Temperature probe connector: Temperature probe cable attaches here.

Front Panel



15. Silence icon: when Silence button is pressed after alarm sounds (silence active), silence icon (bell) lights to indicate that audible alarms have been silenced for 2 minutes.
16. Systolic window: 3-digit red LED indicates measured systolic BP in mmHg.
17. Diastolic window: 3-digit red LED indicates measured diastolic BP in mmHg.
18. Alarm volume indicator: lights to indicate you are making a change to the alarm volume.
19. Pulse volume: lights to indicate you are making a change to the pulse volume.

20. Inflate pressure: lights to indicate you are making a change to the inflation pressure.
21. Pulse Rate window: 3-digit yellow LED shows pulse rate in beats per minute.
22. SpO_2 pulse indicator: Red LED bar flashes to indicate that real-time pulse rate measurements are being derived from SpO_2 signals.
23. SpO_2 window: 3-digit red LED indicates oxygen saturation in %.
24. MAP/Cuff window: 3-digit red LED indicates measured MAP in mmHg and shows instantaneous cuff pressure during BP determination.
25. Min window: Displays the BP mode if manual or STAT is the cycle time when in Auto Cycle mode.
26. Battery power indicator: Green LED indicates the Monitor is operating on battery power.
27. Low battery power indicator: Yellow LED indicates LOW charge status of internal battery.
28. Charging indicator: Green LED indicates presence of external power source and battery charging.
29. Temperature window: 4-digit red LED indicates measured temperature.

Product Compliance

The DINAMAP® ProCare Monitor is classified in the following categories for compliance with IEC 60601-1:

- Internally powered or Class II when powered from external supply
- Transportable
- For continuous operation
- Not suitable for use in the presence of flammable anesthetics
- Not for use in the presence of an oxygen-enriched atmosphere (oxygen tent)
- Type BF applied parts
- IPX1, degree of protection against ingress of water
- Sterilization/Disinfection, see Appendix B
- Software is developed in accordance with IEC 60601-1-4.
- This equipment is suitable for connection to public mains via power adaptors as defined in CISPR 11.
- The SpO_2 parameter conforms to ISO 9919:2005.
- Defibrillation protected. When used with the recommended accessories, the Monitor is protected against the effects of defibrillator discharge. If monitoring is disrupted by the defibrillation, the Monitor will recover.

C US

DINAMAP PROCARE MONITOR
CLASSIFIED WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANCIAL AND OTHER SPECIFIED HAZARDS ONLY IN ACCORDANCE WITH CAN/CSA C22.2 NO. 601.1. ALSO EVALUATED TO IEC 60601-2-30.

CE 0459

This product conforms with the essential requirements of the Medical Device Directive. Accessories without the CE mark are not guaranteed to meet the Essential Requirements of the Medical Device Directive.

Theory of Operation

Introduction

This section provides overall theory of operation and functional description of the ProCare Monitor. The ProCare Monitor comes in six different configurations:

- ProCare 100: capable of monitoring Blood Pressure (BP) and Pulse
- ProCare 200: capable of monitoring Blood Pressure (BP), Pulse, and Temperature
- ProCare 300 Nellcor: capable of monitoring Blood Pressure (BP), Pulse and SPO2 (Nellcor technology)
- ProCare 300 Masimo: capable of monitoring Blood Pressure (BP), Pulse and SPO2 (Masimo technology)
- ProCare 400 Nellcor: capable of monitoring Blood Pressure (BP), Pulse, SPO2 (Nellcor technology), and Temperature
- ProCare 400 Masimo: capable of monitoring Blood Pressure (BP), Pulse, SPO2 (Masimo technology), and Temperature

The model of your monitor determines which parameters are in your monitor.

Using the ProCare Monitor, a clinician can view, print and recall data that is derived from each parameter. The Monitor is also capable of alerting the clinician to changes in the patient's condition. All of the main operations of the ProCare Monitor are easy-to-use and only a button-touch away. Please review the factory default settings and, where applicable, enter settings appropriate for your use.

Overall Principles of Operation

The ProCare Monitor is a portable unit that receives power from an internal rechargeable Lead Acid Battery.

When the ON/OFF button is pressed, the Main Board is brought out of a sleep mode and turns on the power regulators. The power regulators provide conditioned power from the Lead Acid Battery. The external DC source is used only to charge the Lead Acid Battery. Once the ProCare Monitor is energized, a self-test is performed. The self-test automatically tests the main functions of the ProCare Monitor. Failure of the self-test will set the ProCare Monitor into a fail-safe mode with an audio alarm.

Under normal operating conditions, the ProCare Monitor is ready to record the patient vital signs using three external attachments: the temperature probe, SPO2 sensor, and cuff. Interface with a central station or other device is accomplished through the host communication port on the back of the ProCare Monitor.

NOTES

- Prior to each use, inspect the power supply cord to ensure proper connection and condition.
- Be sure to unplug the Monitor before transport.

SpO_2 (Model 300 and 400)

The SpO2 probe has a built-in sensor. When the SpO2 sensor is attached to the SpO2 connector and patient, the probe senses both heart rate and oxygen saturation. The analog signals are routed to the SpO2 PWA (Nellcor or Masimo). The analog signals are analyzed on the SpO2 PWA. The results are digitized and sent to the Main Board via opto couplers. The couplers provide patient isolation as well as serial data interface. The Main Board temporarily stores the data and routes it to the UI Board for display and/or printer.

A reset signal to the SpO2 PWA is also provided so that power up sequencing is correct. If the SpO2 circuit quits communicating to the Main Board, the Main Board will attempt to reset the SpO2 PWA.

Cuff Blood Pressure (BP) and Pulse

The BP parameter in the *ProCare* Monitor is available with two types of DINAMAP BP technologies: one calibrated to intra-arterial pressure and one calibrated to the auscultatory method (specific technologies are available in select markets). All user interface options, instructions for use, and alarms will be the same for both technologies. The BP parameter is included in all models. Blood pressure is monitored noninvasively in the *ProCare* Monitor by oscillometric method.

NOTE: For neonatal populations, the reference is always the intra-arterial pressure monitoring method.

When the cuff and hose are attached to the ProCare Monitor and a Non-Invasive Blood Pressure (NIBP) determination is initiated, the pump inflates the cuff. Pressure transducers PT1 and PT2 monitor pressure information. The pneumatic manifold has one valve, which is used to deflate the cuff. Valve control is through the Main Board. Once determinations are made for the systolic BP and diastolic BP, the Main Board calculates the pulse rate/ Mean Arterial Pressure (MAP). The results are then displayed on the UI Board and sent to the printer (if specified).

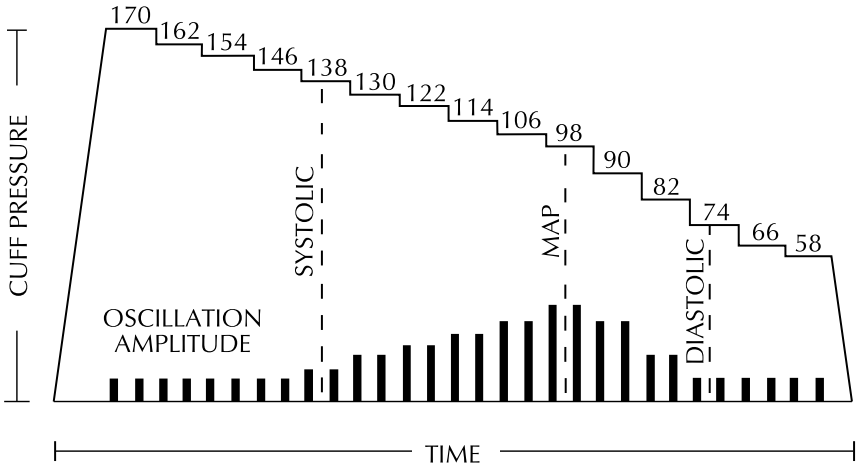
The Pneumatic Valve/Manifold (PVM) device is controlled by the secondary processor. The secondary processor monitors pressure information from PT2. If an over-inflation condition occurs, the OVERPRESSURE signal is routed to the PVM to release the air pressure. The Main Board also generates an alarm condition with the speaker sounding and error code message on the UI Board.

Principles of Noninvasive Blood Pressure Determination

The oscillometric method of determining NIBP is accomplished by a sensitive transducer, which measures cuff pressure and minute pressure oscillations within the cuff. The first determination sequence initially pumps up to a cuff pressure of about 160 mmHg for adult/pediatric patients or 110 mmHg for neonates depending on initial target pressure preset. After inflating the cuff, the Monitor begins to deflate it and measures systolic pressure, mean arterial pressure, and diastolic pressure. When the diastolic pressure has been determined, the Monitor finishes deflating the cuff and updates the screen.

The Monitor deflates the cuff one step each time it detects two pulsations of relatively equal amplitude. The time between deflation steps depends on the frequency of these matched pulses (pulse rate of the patient). However, if the

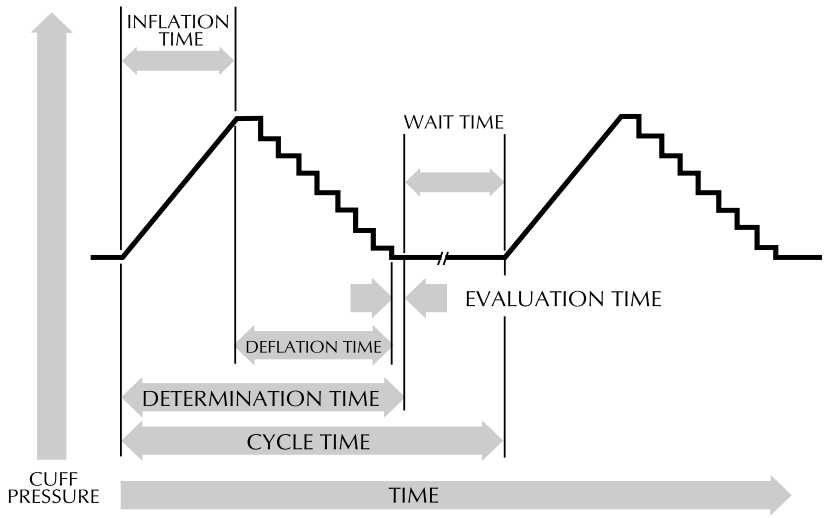
Monitor is unable to find any pulse within several seconds, it will deflate to the next step. The process of finding two matched pulses at each step provides artifact rejection due to patient movement and greatly enhances the accuracy of the Monitor. The figure shows the NIBP determination sequence.



NIBP Determination Sequence

At each step the microprocessor stores cuff pressure, the matched pulse amplitude, and the time between successive pulses. The stepped deflation and matched pulse detection continues until diastolic pressure is determined or total cuff pressure falls below 7 mmHg. The Monitor then deflates the cuff (to zero detected pressure), analyzes the stored data, and updates the screen.

The operating cycle is composed of four parts: inflation time, deflation time, evaluation time, and wait time. Wait time, which varies from mode to mode, is affected by the cycle time (auto mode) or operator intervention (manual mode). The figure shows the basic operating cycle.



NIBP Operating Cycle

Systolic Search

If systolic pressure is not found, the NIBP parameter can search at cuff pressures higher than the initial target pressure. The parameter will inflate the cuff above the initial target pressure to get more data in the systolic region. The maximum pressure allowed in systolic search is limited by the normal range for cuff pressures. In any operating mode, if a patient's systolic pressure exceeds the inflation pressure, the parameter will begin a normal deflation sequence, detect the absence of a systolic value, stop deflation, reinflate to a cuff pressure higher than the initial inflation pressure, and resume the normal deflation sequence.

In any operating mode, if a patient's systolic pressure exceeds the inflation pressure of the monitor, the Monitor will begin normal deflation sequence, detect the absence of a systolic value, stop deflation, reinflate to a higher (than initial) inflation pressure (290 mmHg maximum), and resume normal deflation sequence. This additional inflation will occur only once per determination.

If a previous valid systolic pressure is displayed and less than 2 minutes old, and the new systolic pressure oscillations are compared with the previous valid determination and the Monitor "thinks" that the systolic was not obtained, the Monitor will inflate the cuff to a pressure of an additional 50 mmHg above the immediately preceding inflation. This additional inflation will occur only once per determination.

Reference Used to Determine NIBP Accuracy

To establish accuracy of an NIBP device, manufacturers have used several different types of references. The reference blood pressures may be obtained by invasive pressure monitoring at the central aortic region or at the radial sites. The reference blood pressures may also be obtained by noninvasive methods like auscultatory method (using cuff and stethoscope).

NOTE: For neonatal populations, the reference is always the intra-arterial pressure monitoring method.

DINAMAP® Monitors With Intra-Arterial Reference

(DINAMAP® Classic Technology) – For these monitors, the NIBP is referenced to the invasive blood pressure obtained at the central aortic region.

DINAMAP® Monitors With Auscultatory Reference

(DINAMAP® Auscultatory Technology) – In these monitors, the reference blood pressure is the auscultatory method for adult and pediatric populations. For neonatal populations, the reference is the invasive blood pressure obtained at the central aortic region.

CAUTION

Do not use an infant cuff with an auscultatory reference DINAMAP® *ProCare* Monitor. The neonatal #5 cuff and neonatal hose may be used on patients with an arm circumference of 8 - 15 cm.

Temperature (Model 200 and 400)

The ProCare Monitor uses Alaris Turbo Temp technology to measure patient temperature. The Turbo Temp probe contains a heating element that preheats the probe to reduce determination time. The heating function is controlled by the Main Board. The Turbo Temp probe also contains a thermistor that indicates the temperature. When the probe is attached to the temperature connector and patient, the signal generated by the thermistor is routed to the Main Board. The Main Board converts the thermistor signal along with status information (i.e., ORAL or RECTAL probe indicators) to a DIGITAL signal. The Main Board then processes the DIGITAL signal and displays the patient temperature on the UI Board and printer in Celsius or Fahrenheit.

Host Communication Port

The Host Comm Port is used to interface the ProCare Monitor with other electronic devices (a central nurse's station or remote alarm device.) Signals can be sent to the ProCare Monitor to initiate blood pressure determinations and other functions. Patient data can also be retrieved through this port. For further information, reference the DINAMAP Host Communication manual.

Functional Description

The following paragraphs provide the functional interface relationship. The ProCare Monitor contains a number of electrical & electro-mechanical assemblies. These assemblies are:

- Main Board PWA
- User Interface (UI) Board PWA
- SPO_2 PWA (optional)
- Printer (optional)
- Pneumatic Valve/Manifold (PVM)
- Optical Switch (optional)

Main Board PWA

The ProCare Main Board is based on the Motorola MMC2107 integrated microprocessor. The microprocessor integrates Flash ROM, RAM, A/D converter with input multiplexer, SPI interface, and timers into one chip. This microprocessor is the primary processor for the ProCare Monitor. It services and controls the Patient Parameter Interface (PPI) devices, printer, UI Board, Real Time Clock, audio circuit, and host communication. The secondary processor controls the watchdog, pneumatic safety interlock, timing check, primary processor reset, and power supply control. The secondary processor is powered at all times.

Independent software in the primary and secondary processor periodically communicate when the software systems are operating properly. When either system stops processing or detects an error, it stops communicating with the other. Either system, upon detecting a failure, can assert a safe state (herein called FAILSAFE) of the hardware.

Upon entering a FAILSAFE condition, the Main Board will perform the following tasks:

- Parameter monitoring disabled
- Alarm tone sounding from speaker
- Pneumatic FAILSAFE (deflate the cuff, pump off)
- Normal communications interface disabled
- Remote alarm control inactive
- Hard keys except ON/OFF key inactive

The ON/OFF key can reset the Monitor and end the FAILSAFE condition. The FAILSAFE condition will terminate automatically after 10 minutes to preserve battery power.

All regulated DC power, isolated and non-isolated is generated on the Main Board from Battery supply. The external DC input is used to charge the battery via charging circuitry on the Main Board.

User Interface (UI) Board PWA

The UI Board is used as a message center. It displays patient vital signs, alarms status, monitor set-up, limit violation, BP cycle and the time the data was received. The primary processor on the Main Board controls the UI Board. When the primary processor reads the parameter signals, it decodes the signals and routes the display information to the UI Board.

The UI assembly also provides hardkey switches for the ProCare Main Board. The primary processor asserts a HIGH on the 16 outputs of the 1-of-16 decoder/ demultiplexer one at a time and then reads at the signal on SW_MUX. A LOW on SW_MUX indicates that the switch is asserted.

SPO_2 PWA

The ProCare Monitor can be configured for use with either a Nellcor or Masimo SPO2 PWA. The SPO2 PWA provides continuous readings of oxygen saturation and pulse rate. Additional circuitry on the Main Board provides power, data communications, and isolation between SPO2 PWA and primary processor.

Patient data received from the finger sensor is filtered, amplified, and analyzed on the SPO2 PWA. The information is sent to the Main Board via the optically coupled electrically isolated serial connection. The primary processor receives the data and routes it to the UI board for display. The data is also sent to the printer if specified

Printer

The printer receives power from the Main Board and communicates with the primary processor. Printer presence and print head temperature is indicated by PR_TH signal to the primary processor. When a print command is sent to the printer from the primary processor, the following will occur:

- PR_CLK signal - transfer the data into print head
- PR_DI signal - serial dot to be printed
- PR_LAT signal - latch the data stream into the head
- PR_ST1-6 - cause the head to print various sections
- PR_M1-4 signals - control power sequentially to the two stepper motor windings

Together these signals (CONTROL DATA) cause the printer to print a graphic hardcopy of the patient vital sign values and trend data. It also causes the printer to print a hardcopy of error logging and service record data.

The printer has a built-in sensor to monitor the printer paper presence. When the printer is out of paper, it sends a PAPER OUT signal to the primary processor.

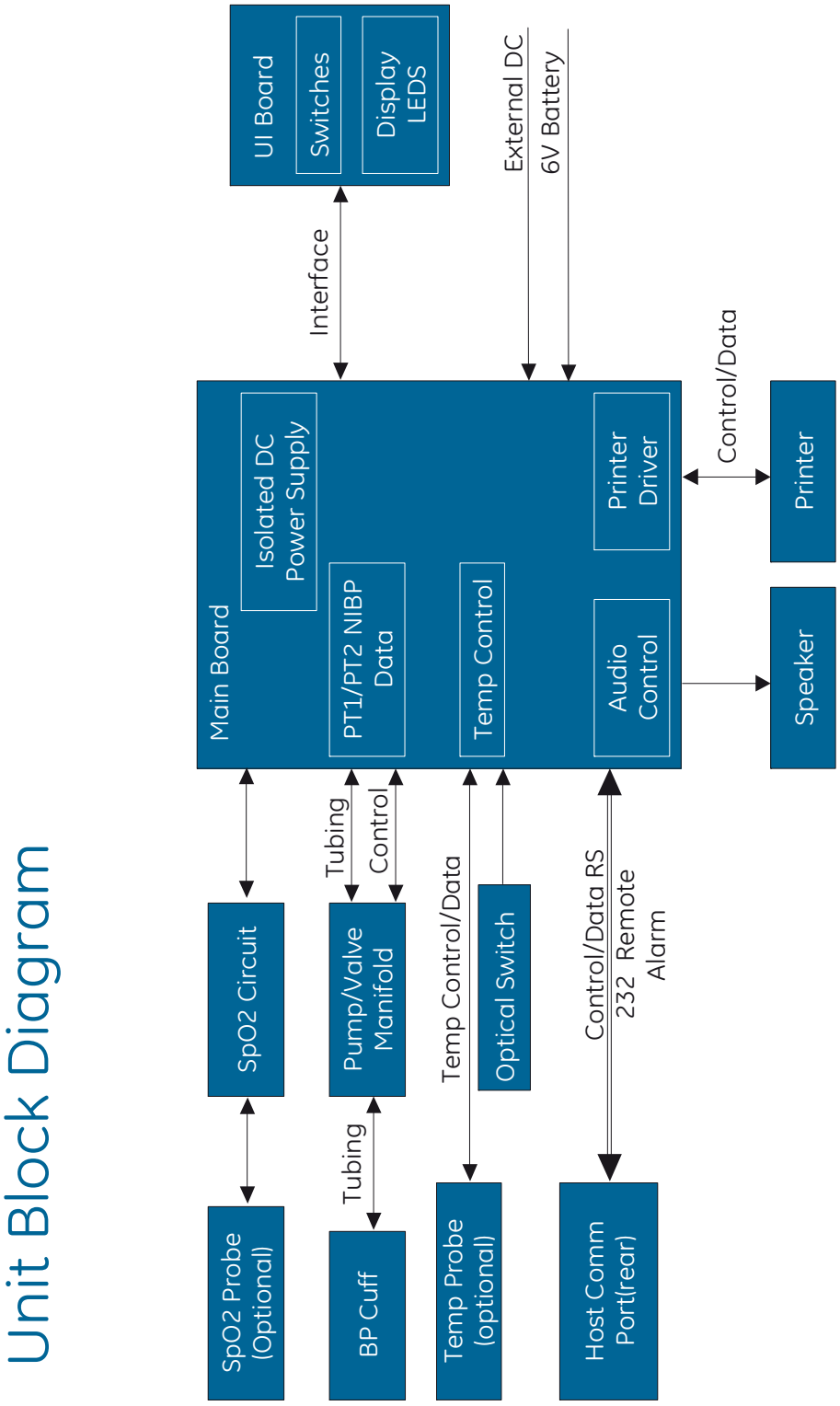
Pneumatic Valve/Manifold (PVM)

The PVM assembly consists of a pump, a deflate valve, and a dump valve. The PVM inflates/deflates the cuff during BP determinations. During normal operation the PVM is controlled by the primary processor. If a failsafe mode or overpressure condition occurs, the secondary processor provides the appropriate control signals to insure a safe condition, where the cuff vents to ambient atmosphere pressure.

Optical Switch

The optical switch indicates whether the temperature probe is inserted in the probe holder or not. The Main Board powers the switch.

Unit Block Diagram

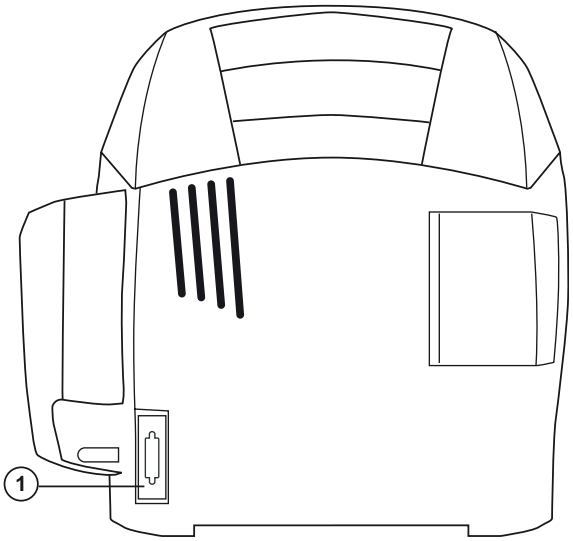


3 Installation

For your notes

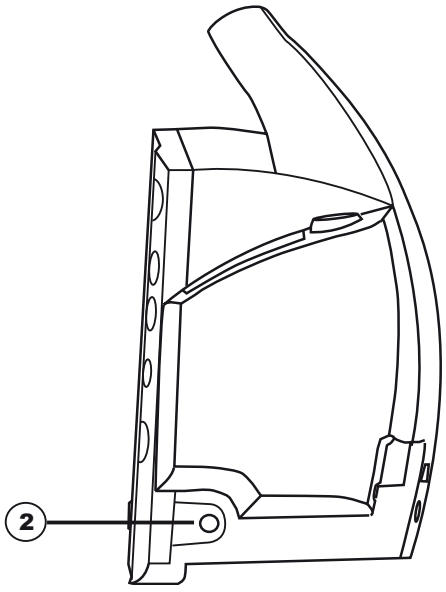
Connections

Rear Panel



1. Data interface connector: Host communications port (15 pin D-type RS-232 serial port) for use only with equipment conforming to IEC 60601-1, configured to comply with IEC 60601-1-1.

Right-Side Panel



2. External DC power socket: To be used with approved GE Medical Systems *Information Technologies* AC-DC power converter ONLY.

Powering the Monitor

Power Sources

The ProCare Monitor is designed to operate from an internal lead-acid battery.

NOTE: The ProCare Monitor is not designed to operate without an internal battery.

Battery Charging

The Monitor charges the Lead-Acid battery whenever the AC power supply is in use. The Monitor automatically senses if the battery needs recharging. Battery charging will continue as long as the Monitor is connected to the AC power supply, even when the Monitor is turned off.

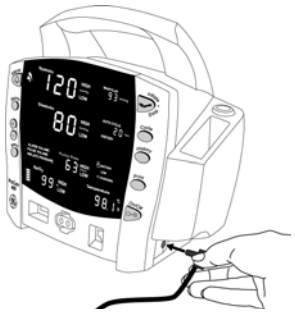
- Batteries should be charged before first use or after long periods of storage.
- The battery should be charged before use, as a charged battery loses some charge when left in storage.
- The battery should be charged at room temperature (59° F - 86° F; 16° C - 30° C).
- It is normal for the battery to become warm during charging or after use.
- Batteries can be charged or topped-off at any time. Battery should not be fully discharged.
- If the Monitor is idle for extended periods, it should be fully charged once a month to ensure optimum performance.
- Prior to each use, inspect the power supply cord to ensure proper connection and condition.

NOTE: Before the ProCare Monitor is used for the first time, the battery should be charged in the Monitor for at least 8 hours.

With external DC power connected, the green **CHARGING** indicator will light to indicate that the battery is charging.

When the Monitor is operating on battery power and the **BATTERY LOW** alarm is not active, the **BATTERY** indicator is backlit green. When the Monitor is operating on battery power and the **BATTERY LOW** alarm is active, the **BATTERY** indicator flashes green, the **LOW** indicator flashes amber, and the medium priority alarm sounds until it is acknowledged. Press the Silence button to acknowledge this alarm. Once it is acknowledged, the indicators continue to flash, but the audible alarm is silenced for 10 minutes. Once the **BATTERY LOW** condition becomes active, the Monitor should be connected to a DC power supply to recharge the battery (refer to “Power Requirements” in *Product Overview* section). If the Monitor continues to be used without charging the battery, the Monitor eventually enters a fail-safe mode (E13: BATTERY TOO LOW TO OPERATE). Refer to the **Alarms** Section for information of an E13 error code.

Battery charging will take place as long as the Monitor remains connected to an external AC power source.



NOTE:: To prolong the life of the battery, keep the Monitor connected to a DC power supply whenever possible. NEVER allow the battery to become completely discharged. A fully charged battery will power the Monitor for approximately 5 hours. To ensure optimum operation (full charge cycles), replace only with a recommended battery. If the Monitor is to be stored for some time, first charge the battery and then remove it and store it separately from the Monitor.

Unpacking and Preparation for Installation

1. Unpack and identify the contents of all shipping materials.
2. Remove the ProCare Monitor.
3. Unpack the AC cord.
4. Plug the AC cord into the AC Mains input at the back of the Monitor.
5. Plug the AC cord into a Hospital Grounded AC receptacle. The word CHARGING will illuminate green on the front of the Monitor indicating that an AC source is available.

Prior to usage it is necessary to charge the Monitor for 12 hours. This charge calibrates the battery charging circuitry with the charge status of the battery.

Configuring Your ProCare Monitor

Operating Modes

The ProCare Monitor can operate in one of four modes: clinical, configuration, advanced configuration, and service.

Clinical Mode

Clinical mode is the Monitor's normal operating mode. While this mode is active, alarm limits and a few other commonly used settings are adjustable. All parameters are available for monitoring in this mode.

Configuration Mode

Configuration and advanced configuration modes display the software revision and allow you to configure defaults for some settings that are available in clinical mode, as well as some less commonly used settings that are only adjustable in these modes. A fatal error history is also available in the advanced configuration mode. No parameters are operable in these modes, therefore, patient monitoring should be suspended.

Configuration Mode Settings

Monitor settings such as HIGH/LOW alarm settings changed in the Clinical Mode will not be retained after the monitor is powered off. To retain alarm and parameter settings, the changes must be done in the configuration mode. Date/ Time settings are also entered in the configuration mode.

To enter the configuration mode: with the Monitor off, press and hold the **Menu** button at the same time as pressing and holding the **On/Off** button for 3 seconds. The Monitor enters the configuration mode.

For a few seconds immediately after power up in this mode, the Systolic and Diastolic windows display the major and minor version codes. The version codes are numbers that represent the letters of the English alphabet, which are designated to the currently loaded version of the monitor firmware (e.g., 1 indicates A, 2 indicates B, etc.).

At the same time, **AUSC** appears in the "min" (minutes display) window if the monitor is configured with auscultatory BP. That area appears blank for a monitor with classic DINAMAP BP configuration.

Display	**Window**
Major software revision	Systolic
Minor software revision	Diastolic
Type of BP technology	min

These displays appear only during the first part of the power up sequence and are not selectable and cannot be changed. After a moment, this version information is cleared, and the monitor displays the 1st page of configuration mode which simply displays **CFG** in the Systolic window.

Pressing the **Menu** button cycles through all the configuration option pages. After all options pages have been displayed, the display returns to the 1st configuration mode page (displaying **CFG**). You can use the **+** and **-** buttons to make changes to settings. After making changes, simply cycle the power to return to normal operation (clinical) mode. Changes are automatically retained.

The Menu selections appear in the following order. Refer the each manual section for settings options.

NOTE: Menu selections for a Masimo unit have three SpO_2 settings. Refer to the Masimo SpO_2 section for options.

Setting:	Window	LED Display
• Inflate Pressure:	Diastolic	XXX (numeric)
• SpO_2 Mode:	SpO_2	nOd
• SpO_2 Sat:	SpO_2	SAt
• SpO_2* Sensitivity:	SpO_2	SEn
• Temp:	°C or °F	Unt
• Year:	Systolic	Yr
• Month:	MAP/Cuff	MtH
• Day:	Diastolic	dAY
• Hour:	min	Hr
• Minute:	min	Min
• Mode:	Systolic	CFG

*Masimo units only

Setting the Date and Time – To set the date and time on the ProCare Monitor, you must access the configuration mode. Press **Menu** to skip the default settings that do not require changes. The following list shows the windows in which the date/time settings appear.

Setting:	Window	LED Display
• Year:	Systolic	Yr
• Month:	MAP/Cuff	MtH
• Day:	Diastolic	dAY
• Hour:	min	Hr
• Minute:	min	Min

Procedures

1. Press the **Menu** button to move from one setting to another. Use the **+/-** buttons to increment or decrement the setting.

   NOTE: For the date and time to be saved, you must advance the menu through the minute setting.

2. To exit the configuration mode, press the **On/Off** button.
3. To continue with other changes, press the **Menu** button. **CFG** will appear in the Systolic window. To change parameter settings, press the **Menu** button and select the parameter function. To change alarm settings, press the **Alarms** button.

Inflation Pressure Default Setting –

Procedures

1. Enter the configuration mode: with the Monitor off, press and hold the **Menu** button at the same time as pressing and holding the **On/Off** button for 3 seconds, or press **Menu** until the Inflate Pressure is lit on the display and the pressure is displayed in the Diastolic window.
2. Use the **+/-** buttons to increment or decrement the inflate pressure default setting. Increments are 5mmhg from 100mmhg to 250mmhg.
3. To exit the configuration mode, turn the unit off. To continue with additional configuration settings, press **Menu**.

Alarm Default Settings –

Procedures

1. Enter the configuration mode: with the Monitor off, press and hold the **Menu** button at the same time as pressing and holding the **On/Off** button for 3 seconds. After the unit enters the configuration mode, press **Alarms**. At any point in the configuration mode menu, Alarms default can be selected.
2. To set or change the default setting, press the Alarms button to select alarm setting. Use the **+/-** buttons to increment or decrement the individual settings.

   NOTE: For the Alarms default setting to be saved, you must advance the menu through the SPO2 settings.
3. To exit the configuration mode, turn the unit off. To continue with additional configuration settings, press **Menu**.

SpO_2 Configuration Settings –

Procedure for units with Nellcor® Technology

(Refer to the Nellcor® section for options)

1. Enter the configuration mode: with the Monitor off, press and hold the **Menu** button at the same time as pressing and holding the **On/Off** button for 3 seconds.
2. Press the menu button until **n0d** appears in the **Pulse Rate** window.
3. Use the **+/-** buttons to select the option.
4. Press the **Menu** button once. **SAt** appears in the **Pulse Rate** window.
5. Use the **+/-** buttons to select the option.
6. To exit the configuration mode, turn the unit off. To continue with additional configuration settings, press **Menu**.

Procedure for units with Masimo® Technology
(*Refer to the Masimo® section for options)*

1. Enter the configuration mode: with the Monitor off, press and hold the **Menu** button at the same time as pressing and holding the **On/Off** button for 3 seconds.
2. Press the **Menu** button until **n0d** appears in the **Pulse Rate** window.
3. Use the **+/-** buttons to select the option.
4. Press the **Menu** button once. **SAt** appears in the **Pulse Rate** window.
5. Use the **+/-** buttons to select the option.
6. Press the **Menu** button once. **SEn** appears in the **Pulse Rate** window.
7. Use the **+/-** buttons to select the option.
8. To exit the configuration mode, turn the unit off. To continue with additional configuration settings, press **Menu**.

Advanced Configuration Mode

Advanced Configuration mode is entered by holding the **Menu** button and the **-** button simultaneously while powering on with the **On/Off** button.

For a couple of seconds immediately after power up in this mode the Systolic and Diastolic display windows will display the major and minor version codes. The version codes are numbers that represent the letters of the English alphabet which are designated to the currently loaded version of the monitor firmware (e.g., 1 indicates A, 2 indicates B, etc.).

After a moment, this version information is cleared, and the monitor displays the 1st page of configuration mode which simply displays **ACF** in the Systolic display window indicating that the monitor is in advanced configuration mode.

You can then press the **Menu** button to cycle through all the advanced configuration mode option pages. After all options pages have been displayed, the display will return to the 1st advanced configuration mode page (displaying **ACF**). You can use the **+** and **-** buttons to make changes to settings. After making changes, simply cycle the power to return to normal operation mode. Changes are automatically be retained.

The advanced configuration mode option pages are as follows:

Displayed on Monitor	Function
ACF	Advanced Configuration Mode announcement (No settings are entered on this page.)
rEM	Remote mode 0 : Remote mode is disabled 1 : Remote mode is enabled
Adr	Host Comm unit address 32 : This is the default value.
br	Host Comm bit rate (bits per sec) 0 : 300 bps 1 : 600 bps 2 : 1200 bps 3 : 2400 bps 4 : 4800 bps 5 : 9600 bps (default) 6 : 19200 bps
Mod	Host Comm mode 0 : Host Comm Command mode (default) 1 : 1846 Compatibility mode (1846 mode requires user to also select 600 bps.)

Service Mode

Service mode is entered by holding the **Cycle** button while powering on with the **On/Off** button. You can press the **Cycle** button to advance through the available service mode pages.

NOTES

- Only transducer calibration pages are available until calibration is valid.
- Calibration and other service mode setting changes will not be retained unless the "Save Settings" operation is executed (on the final Service Mode options page).

After all options pages have been displayed, the display will return to the 1st service mode page (initial calibration page). To save service mode settings the Service Mode option pages are as follows:

Displayed on Monitor	Function
0 (in "min" window)	Refer to calibration section for functions.
1 (in "min" window)	
2 (in "min" window)	
3 (in "min" window)	NIBP Algorithm Type loaded (Displayed in Systolic display window) 1: Classic DINAMAP NIBP 2: Auscultatory NIBP (This setting cannot be changed.)
4 (in "min" window)	SpO_2 Type loaded (Displayed in SpO_2% display window) 0: No SpO2 1: NellCor 2: Masimo (Warning: Incorrect setting will cause fatal 930 alarm during operation.)
5 (in "min" window)	Temperature loaded (Displayed in Temperature display window) 0: No Temp 1: Turbo Temp

Displayed on Monitor	Function
6 (in “min” window) In “MAP/Cuff” window: # of remaining saves possible.	Language The number displayed in Pulse Rate display window indicates the language setting. These range from 0 to 20. For example, 0 indicates English. The language setting is used in printed reports. 0 English 1 Chinese 2 Czech 3 Danish 4 Dutch 5 Finnish 6 French 7 German 8 Greek 9 Hungarian 10 Italian 11 Japanese 12 Korean 13 Norwegian 14 Polish 15 Portuguese Brazilian 16 Portuguese Continental 17 Russian 18 Slovak 19 Spanish 20 Swedish **Warning:** The number displayed in the “MAP/Cuff” window will decrease each time the “Save Settings” operation is done. If it reaches zero, a fatal 975 alarm (calibration space exhausted) results and the unit will have to be serviced before operation will be possible again.

Host Communications Connector

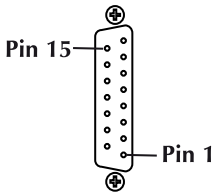
All host port signals are NON-ISOLATED and should be connected to equipment conforming to IEC 60601-1-1 ONLY. Where isolation of data communication is required, the isolated level converter should be used. If external alarm control is required, p/n 487208 (Isolated Remote Alarm Cable Assembly) should ALWAYS be used. Please refer to the Information Sheet included with the isolated remote alarm cable for operational details.

NOTE: When using remote alarm, the ProCare Monitor should be considered the primary alarm source. The secondary alarm is used for secondary purposes only.

DB15 Connector Pin Assignments

Connection Details

Host Port Connector (rear panel)



WARNING! Auxiliary equipment connected to the DINAMAP® ProCare Monitor will result in the formation of an electromedical system and thus, must comply with the requirements of EN 60601-1-1/ IEC 60601-1. All host port signals are NON-ISOLATED and should be connected to equipment conforming to IEC 60601-1, configured to comply with IEC 60601-1-1 ONLY. Where isolation of data communication is required, GE Medical Systems *Information Technologies* part number ILC1926 should be used. If external alarm control is required, GE Medical Systems *Information Technologies* part number 487208 (Isolated Remote Alarm Cable. When a high-priority alarm condition is displayed on the Monitor, the remote alarm signal becomes active within 0.5 seconds. The active state of the alarm signal is an open circuit. In the inactive state the alarm signal is connected to ground. Please refer to the Information Sheet included with the isolated remote alarm cable for operational details.

NOTE: When using remote alarm, the ProCare Monitor should be considered the primary alarm source. The secondary alarm is used for secondary purposes only.

Pin #	Function
1	Common
2	Inverted TTL Transmit Data
3	Inverted TTL Receive Data
4	+5 volts
5	No connection
6	No connection
7	Common
8	Remote Alarm
9	No connection
10	No connection
11	RS232 Transmit Data (TxD)
12	No connection
13	RS232 Receive Data (RxD)
14	No connection
15	No connection

4 Maintenance

For your notes

Preventative Maintenance

WARNING
Failure on the part of all responsible individuals, hospitals or institutions, employing the use of this device, to implement the recommended maintenance schedule may cause equipment failure and possible health hazards. The manufacturer does not, in any manner, assume the responsibility for performing the recommended maintenance schedule, unless an Equipment Maintenance Agreement exists. The sole responsibility rests with the individuals, hospitals, or institutions utilizing the device.

General

Preventative maintenance tasks include cleaning the ProCare Monitor, checking pressure calibration, pneumatic leakage, pneumatic system overpressure point, temperature calibration (200 and 400), and verification of the SpO_2 system (300 and 400). Perform the following maintenance procedures as required.

Integrity of Hoses and Cuffs

When the pneumatic integrity of any BP cuff and hose is in doubt, replace the cuff and hose, and discard the questionable accessories.

Visual Inspection

The monitor and its components should be carefully inspected prior to installation, once every 12 months thereafter and each time the equipment is serviced.

- Carefully inspect the equipment for physical damage to the case, the display screen, and the keypad. Do not use the monitor if damage is determined. Refer damaged equipment to qualified service personnel.
- Inspect all external connections for loose connectors or frayed cables.
- Have any damaged connectors or cables replaced by qualified service personnel.
- Inspect the display face for marks, scratches, or other damage.
- Physical damage to a flat panel display glass may pose an implosion hazard. Have the flat panel display replaced by qualified service personnel if necessary.
- Safety labels and inscription on the device are clearly legible.

Cleaning

Cleaning the Monitor

CAUTIONS

- Never pour or spray water or any cleaning solution on the equipment or permit fluids to run behind switches, into connectors, into the recorder, into the temperature probe well, or into any ventilation openings in the equipment.
- Do not let fluid “pool” around connection pins.
- Never immerse monitor or accessories in any liquid.
- Do not attach the monitor or accessories to a patient until it is thoroughly dry.

WARNING

Failure to follow these cleaning recommendations may melt, distort, or dull the finish of displays and cases; blur lettering on labels; embrittle cases and lead to cracks and breakage; or cause equipment failures. Use of non-approved cleaning agents is not considered normal wear and repair or replacement of parts is not covered under warranty.

Cleaning Recommendations

Monitor Exterior

Disconnect the monitor from AC power before cleaning or disinfecting its surface. The exterior surfaces of DINAMAP Monitors may be cleaned with a dampened, lint-free cloth. Wipe off all cleaning solutions with a clean, dry cloth and let air dry for at least 15 minutes. Use one of the following approved solutions:

- Mild soap (diluted)
- Commercial diluted bleach solution or bleach wipe
- Commercial diluted ammonia solution
- 10% solution of household bleach (5.25% sodium hypochlorite) in distilled water

Never use the following cleaning agents:

- Abrasive cleaners or solvents of any kind
- Acetone
- Ketone
- Betadine
- Alcohol- or petroleum-based cleaning agents

- Any type of solution that contains ammonium chloride, conductive solutions, wax or wax compounds
- Sodium salts

NOTE: Never autoclave or steam clean the monitor, cuffs, or accessories.

Display

To clean the display screen, use a soft, clean cloth dampened with a glass cleaner. Never spray the glass cleaner directly onto the display, and never use alcohol or petroleum based products.

Cuffs

General

The cuff must be thoroughly cleaned with the specified detergent before reuse. The additional use of household bleach as described below provides at least intermediate-level disinfection.

- Apply cuff hose plugs before cleaning.
- The following cleansing procedure was repeated 20 times on DURA-CUF® Blood Pressure Cuffs and once on SOFT-CUF® Blood Pressure Cuffs without affecting the performance of the cuff.
- While this procedure is adequate for cleaning/disinfection, it may not remove all stains.
- Do *not* immerse hoses.
- Do *not* immerse cuffs without prior application of cuff hose caps.

Materials

- Enzymatic detergent such as ENZOL* enzymatic detergent (US) or Cidezyme* enzymatic detergent (UK)
- Distilled water
- 10% solution of household bleach (5.25% sodium hypochlorite) in distilled water
- Soft cloths and soft-bristled brushes
- Spray bottles

Procedure

1. Prepare the enzymatic detergent according to the manufacturer's instructions and the 10% bleach solution, in separate spray bottles.
2. Spray the detergent liberally on device. If the material is dried on, allow the cuff to sit for 1 minute. For soil on the soft part of the closure or the cuff itself, wipe the material off with a soft cloth. For persistent contamination on the soft part of the closure, use a soft-bristled brush to loosen particles. Rinse with copious amounts of distilled water. Repeat until no visible contamination remains. For soil on the hook part of the closure, use a soft-bristled brush to remove the material, and rinse with copious amounts of distilled water. Repeat until no visible contamination remains.

3. Spray the 10% bleach solution on the affected area until the area is saturated. Allow the cuff to sit for 5 minutes.
4. Wipe away any excess solution and rinse the cuff again with distilled water. Allow 2 hours for drying.

The user has the responsibility to validate any deviations from the recommended method of cleaning and disinfection.

For additional information on infection control procedures, contact GE Medical Systems *Information Technologies* Technical Support.

Temperature Devices

Do not immerse predictive temperature probes. The probe may be cleaned with a solution of 10% bleach in water. Use a cloth or sponge—just damp, not wet—and avoid getting any liquid into the interior of the probe.

SpO_2 Sensors

Adhesive sensors are sterile and for single use only. Reusable sensors should be cleaned before reuse with a 70% alcohol solution. If low-level disinfection is required, use a 1:10 bleach solution. Do not use undiluted bleach (5% - 5.25% sodium chlorite) or any cleaning solution other than those recommended here because permanent damage to the sensor could occur. Do not sterilize the sensor by irradiation, steam, or ethylene oxide. If disposable sensors or their packaging are damaged, they must be disposed of as advised in this appendix.

To clean or disinfect the sensor:

1. Saturate a clean, dry gauze pad with the cleaning solution. Wipe all surfaces of the sensor and cable with this gauze pad.
2. Saturate another clean, dry gauze pad with sterile or distilled water. Wipe all surfaces of the sensor and cable with this gauze pad.
3. Dry the sensor and cable by wiping all surfaces with a clean, dry gauze pad.

Long-Term Storage

If it becomes necessary to store the Monitor for an extended period of time, remove all attached accessories. Attach the original packing inserts, and place the Monitor into the original shipping container.

Battery life is significantly reduced if the battery is left in a discharged state. For long-term storage, fully charge the battery, then remove the battery from the unit and periodically charge the battery. For more information, refer to the "Storage and Battery Care" section below.

Long-term storage at high temperatures can lead to deterioration of seals and separators and should be avoided.

Battery Care

If it becomes necessary to store the Monitor for an extended period of time, first fully charge, then remove the battery. Then store the Monitor and the battery in the original packaging materials.

Batteries should always be fully charged before being placed in storage. Batteries should not be left in storage more than 6 months without removal and full recharge. A fully charged battery in good condition will provide sufficient power to operate a Monitor for approximately 5 hours, including temperature and BP measurements made at 5-minute intervals.

It is best to keep the battery charged as fully as practical and never store the Monitor with the battery in a discharged condition. When the battery will no longer hold a charge, remove and replace it. Failure to replace the battery with the same GE Medical Systems *Information Technologies* part number may result in shorter battery life. Battery charging will take place as long as the Monitor remains connected to an external DC power source.

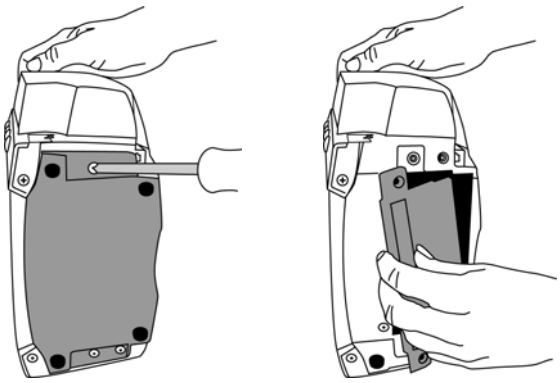
NOTE: After replacing batteries, an E00 error code is normal. The user settings and date/time revert to the factory default setting.

CAUTIONS

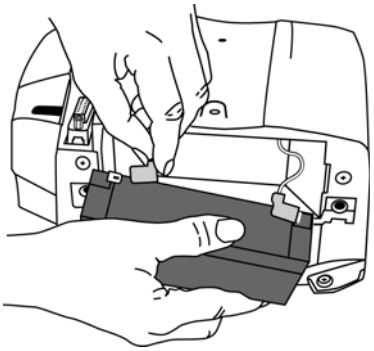
- To ensure that the battery will be ready for portable operation, keep the Monitor connected to a mains supply whenever possible.
- Repeated failure to fully charge the battery will result in a significant reduction in battery life.
- The expected lifetime of the battery largely depends on the way in which the Monitor is used. Never fully discharge the battery. To prolong battery life, connect the Monitor to AC power source when not in use.

Replacing the Battery

1. Unplug the Monitor from the DC power source.
2. Looking at the bottom of the ProCare Monitor, remove the battery compartment cover by removing the four screws that secure the cover and help card tray.
3. Remove the help card tray and battery door cover.



4. Remove the old battery and disconnect the wires. Attach the battery wires to the new battery, ensuring the red terminal (+) is connected to the red wire and the black terminal (-) is connected to the black wire.
5. Insert the battery into the compartment.



6. Then replace the cover, help card tray, and screws. Insert the external DC power converter plug into the external DC power socket and plug into an AC outlet.

   NOTE: Error code E00 appears (Memory Lost) alerting you that the user settings (including alarm limits and inflation pressure) and date/time will go back to factory default values.

7. Reset the date/time and applicable user settings.

CAUTION
Do not touch either the pin of the DC input connector or the terminals within the battery compartment and the patient at the same time.

Replacement batteries can be obtained from GE Medical Systems *Information Technologies*.

NOTE:: The replacement part number of the battery is 633178CR. Use of nonspecified batteries can cause internal damage to the Monitor or cause patient/user safety issues.

Fuses

The Monitor contains four fuses. The fuses are auto-resettable and mounted within the Monitor. The fuses protect the low voltage DC input, the battery, the remote alarm output, and the +5 V output on the host port connector.

Parameter Level Functional Testing

After the initial configuration is complete, perform functional testing of each of the parameters, using the accessories supplied with the ProCare Monitor.

Refer to the operation manual for more detailed parameter-specific instructions.

BP

Perform a blood pressure by connecting the supplied hose and cuff together, then attaching to the front of the ProCare Monitor. Press the **Start** button on the front to begin the BP cycle.

Temperature

Connect the supplied temperature probe to the corresponding connection. A predictive temperature will begin once the probe is removed from its holster. Place the probe in the holster after completion of the Temp cycle.

Nellcor SpO_2 Technology

The SpO_2 sensor is an assembly consisting of two parts: the DS-100A sensor and the DOC-10 extender cable. Connect the cables prior to attaching to the Monitor. A SpO_2 reading will be displayed within moments of attaching the sensor to either a Nellcor simulator or to your finger.

Masimo SpO_2 Technology

The SpO_2 sensor is an assembly consisting of two parts: the LNOP NR-195 sensor and the PC08 extender cable. Connect the cables prior to attaching to the Monitor. A SpO_2 reading will be displayed within moments of attaching the sensor to either a Nellcor simulator or to your finger.

Calibration Procedures and Tests

NOTE: All devices are tested and calibrated during manufacturing and are certified for operation at installation.

- To adequately test the safety and integrity of the ProCare Monitor, the following test equipment is recommended:
- 12VDC power supply
- IEC 60601-1 approved leakage tester
- Digital manometer (with range to 350 mmHg)
- Stopwatch/timer (capable of measuring seconds)
- Adult BP cuff, Neonate BP cuff, hose, inflation bulb, and associated tubing
- Calibration kit (p/n 320246, available through GE Medical Systems
- SpO_2 cable (for appropriate SpO_2 type, if SpO_2 is installed)
- TE 1811 Temperature Probe Simulator (if TEMP is installed) available from Alaris™
- Printer paper (if PRINTER is installed)
- 3" diameter rigid cylinder (mandrel)

CAUTION
Calibration equipment should always be kept dry and free of particulate matter. Moisture or foreign substances introduced to the pneumatic system will likely cause damage to the Monitor and/or the accessories.

Annual Procedures

Perform the following test procedures every 12 months, or whenever the accuracy of any reading is in doubt.

Parameter Test Procedures

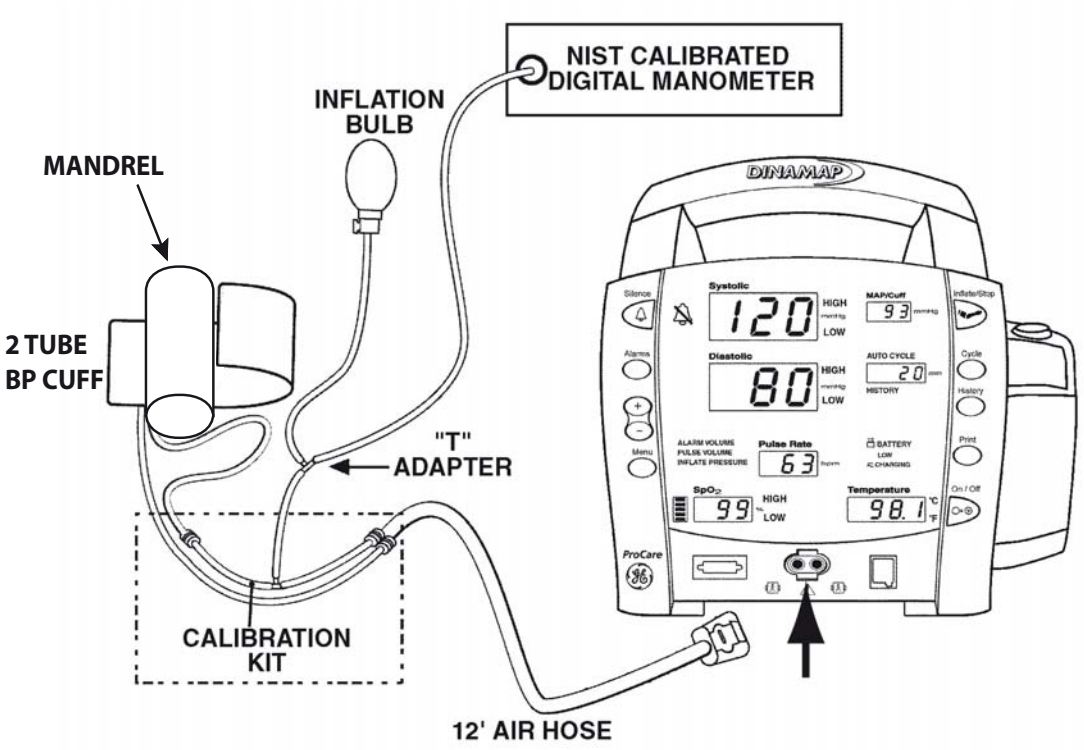
Complete the Test Record at the end of this section as tests are performed.

NOTES
- This test is written so that a knowledgeable technician who is familiar with the ProCare Monitor and the test equipment and will be able to follow the test procedure.
- To enter Service Mode press and hold **Cycle** button while pressing the **On/ Off** button.

Setup

1. Connect manometer to unit as shown.
2. 'T' an inflation bulb into the pneumatic setup.

3. Consult the following diagram for pneumatic setup guidelines.



Leakage Testing

NOTE: To enter Service Mode press and hold the **Cycle** button while pressing the **On/Off** button.

1. Turn unit on and enter Service Mode.
2. Press **Cycle** button and **1** should appear in the **min** window.
3. Close the valve on the inflation bulb.
4. Using the inflation bulb, inflate the system to 210 mmHg.
5. Allow the system to stabilize for 5 seconds (it is normal to see some decrease in pressure at this point).
6. Start the stopwatch and record the pressure value.
7. After 60 seconds record the pressure value.
8. The leakage rate is the difference between the first and second readings.
9. Record and verify the leakage rate.
10. Turn the ProCare Monitor off.

Pressure Transducer Verification

NOTE: To enter Service Mode press and hold the **Cycle** button while pressing the **On/Off** button.

1. Turn unit on and enter Service Mode.
2. The **min** window should display **0**.
3. Open the valve on the inflation bulb and remove all pressure from the system (manometer reads zero).
4. Press **Cycle** button and **1** should appear in the **min** window.
5. Use the inflation bulb to inflate the cuff, hose and pressure indicator setup to 200 mmHg.
6. Record and verify the pressure reading that appears in the top **Systolic** window.
7. Record and verify the pressure reading that appears in the top **Diastolic** window.
8. Use the valve on the bulb to reduce pressure to 150 mmHg.
9. Record and verify the pressure reading that appears in the top **Systolic** window.
10. Record and verify the pressure reading that appears in the top **Diastolic** window.
11. Use the valve on the bulb to reduce pressure to 100 mmHg.
12. Record and verify the pressure reading that appears in the top **Systolic** window.
13. Record and verify the pressure reading that appears in the top **Diastolic** window.
14. Use the valve on the bulb to reduce pressure to 50 mmHg.
15. Record and verify the pressure reading that appears in the top **Systolic** window.
16. Record and verify the pressure reading that appears in the top **Diastolic** window.

Pressure Transducer Calibration

Perform only if Pressure Transducer Verification is out of tolerance as specified in Test Results Table at the end of this section.

NOTE: To enter service mode press and hold **Cycle** button while pressing the **On/Off** button.

1. Turn the ProCare Monitor on and enter Service Mode.
2. The **min** window should display **0**.
3. Open valve on bulb to open pressure system to atmosphere.
4. Verify the manometer reads zero.
5. Press **Cycle** button and **1** should appear in the **min** window.

6. Close valve on bulb and slowly inflate pressure to 200 mmHg (using the manometer as reference).
7. Press **Menu** button when pressure reads exactly 200 mmHg to save calibration setting.
8. Press **Cycle** button until **6** appears in the **min** window.
9. Press and hold **Menu** button until monitor beeps, which acknowledges that data was saved.
10. Turn the Monitor off.

Overpressure Verification

NOTE:: To enter service mode press and hold **Cycle** button while pressing the **On/Off** button.

1. Wait a few seconds after entering service mode. Press **Cycle** button so that the min window changes from **0** to **1**.
2. Use the inflation bulb to inflate close to 300 mmHg. Slowly inflate (1 to 2 mmHg/sec) until valve opens and pressure is released.
3. Record and verify pressure at which valve opens.
4. Press **Cycle** button and **2** should appear in the **min** window.
5. Use the inflation bulb to inflate close to 150 mmHg. Slowly inflate (1 to 2 mmHg/sec) until valve opens and pressure is released.
6. Record and verify pressure at which valve opens.
7. Turn unit off.

Button Testing

1. Disconnect the cuff/hose assembly and power on the unit.
2. Press **Inflate/Stop** button.
3. Verify a BP determination has been initiated.
4. Block pump port and verify **E80** alarm.
5. Verify flashing red indicator of **Silence** button.
6. Press **Silence** button, verify alarm has been removed.
7. Press **Alarm** button several times, verify unit cycles through all alarm settings (i.e., SYS, DIA, SpO_2).
8. Turn unit off.

LED Tests

1. Power on the Monitor.
2. During the power-up self-test verify all 7 segment LED display segments and all discrete LEDs (except CHARGING LEDs) illuminate.
3. Repeat power up cycle until all LEDs are checked.

External DC Verification

1. Plug the power brick into the Monitor.
2. Verify that the CHARGING indicator is illuminated.

BP Determination

NOTE: For best results, it is important to be seated and not moving, talking, eating, and/or smoking, etc. while taking your blood pressure. If you are uncertain as to the proper technique, consult the operation manual.

1. Remove the calibration set up and attach a normal adult cuff and hose (be sure to select the correct cuff size).
2. Press **Start/Stop** button on monitor to begin a determination.
3. Record **Systolic**, **Diastolic**, map and heart rate from the Monitor display.
4. Wait 1 minute, then press **Cycle** button to initiate a determination in Auto BP mode.
5. Record **Systolic**, **Diastolic**, map and heart rate from the Monitor display.
6. Wait 1 minute, then press **Cycle** button until **st** is displayed in the **min** window to initiate a determination in STAT mode.
7. Record **Systolic**, **Diastolic**, map and heart rate from the Monitor display.
8. Press **Start/Stop** button, end STAT mode.

BP Overpressure Verification

1. Remove the cuff/hose from the monitor, restrict airflow from cuff hose port.
2. Press **Start/Stop** to begin BP determination.
3. Verify **E80** is displayed on the **Systolic** window and audible alarm sounds.
4. Remove the air restriction.
5. Press **Start/Stop** and verify that the pump does not start.
6. Press the **Silence** button.
7. Press the **Silence** button again.
8. Verify the alarm condition is cleared from the **Systolic** window.

Temperature (Perform if equipped with Temp module)

The Temperature Simulator for the Alaris System is available from Alaris Medical Systems, Inc. (619) 458-7000.

The Alaris Turbo Temp probes cannot be calibrated. These probes must be discarded after 2 years from the date of manufacture stamped into the RJ45 connector (first two digits=year, second two digits=week). Refer to the illustration example (0520=fw20 in 2005).

It is the responsibility of the user to maintain proper records.

Alaris Turbo Temp Probe Date Code

1. Turn Monitor off. Make sure the temp probe is properly stored in the probe well.
2. Disconnect the temp probe cable from the monitor.
3. Connect Temp simulator; set to 80.2°F.
4. Turn the Monitor on.
5. Put the Monitor into temp monitor mode:
   a. partially remove the probe from the well (stop when you hear the Monitor beep).
   b. Quickly re-insert the probe and remove again (you should hear two beeps of a different tone).
   c. A temperature value should appear quickly, if not, repeat Step 5b.
6. Record and verify the reading in the temp display is 80.2°F ±0.2°F.
7. Set the simulator to 98.6°F.
8. Record and verify the reading in the temp display is 98.6°F ±0.2°F.
9. Set the simulator to 107.8°F.
10. Record and verify the reading in the temp display is 107.8°F ±0.2°F.
11. Calibration is complete. If the monitor does no pass the calibration verification then contact Technical Support.

SpO_2 (Perform only if equipped with SpO_2 module)

1. Connect the appropriate SpO_2 probe and cable to the SpO_2 connector. Place the probe on your finger.
2. Verify the unit displays a:
   - Pulse value
   - Saturation value
   - Signal Strength Bar Graph
3. Remove the sensor from your finger to generate an **E23** alarm and to sound the speaker.
4. Press the **Silence** button.
5. Verify the sound has stopped and the **E23** error is cleared.
6. Re-apply the SpO_2 sensor to your finger.
7. Verify the unit displays a:
   - Pulse Value
   - Saturation value
   - Signal Strength bar Graph

Printer Output Test

1. Load Paper into the print mechanism.
2. Press **Print** button.
3. Verify the printer outputs a record and print quality is good.

Temp Circuit Leakage Test

1. Setup an IEC 60601-1 approved leakage tester to apply 240 VAC to an isolated circuit.
2. Plug temp probe Hi Pot adapter into the temp jack.
3. Record and verify the temp circuit leakage current.

SpO_2 Circuit Leakage Test

1. Setup an IEC 60601-1 approved leakage tester to apply 240 VAC to an isolated circuit.
2. Plug an SpO_2 cable into the SpO_2 connector on the front of the unit.
3. Plug SpO_2 probe Hi Pot adapter in to the DB9 jack at the end of the SpO_2 cable.
4. Record and verify the SpO_2 circuit leakage current.

Test Results Form

Description	Min	Max	Actual	Pass-Fail-N/A
LEAKAGE				
Leakage Result (mmHg)	0	6		
PRESSURE TRANSDUCER VERIFICATION				
Pressure reading at 200mmHg, top display - Systolic	197	203		
Pressure reading at 200mmHg, bottom display - Diastolic	197	203		
Pressure reading at 150mmHg, top display - Systolic	147	153		
Pressure reading at 150mmHg, bottom display - Diastolic	147	153		
Pressure reading at 100mmHg, top display - Systolic	97	103		
Pressure reading at 100mmHg, bottom display - Diastolic	97	103		
Pressure reading at 50mmHg, top display - Systolic	47	53		
Pressure reading at 50mmHg, bottom display - Diastolic	47	53		
OVERPRESSURE VERIFICATION				
Overpressure threshold, Adult (mmHg)	305	325		
Overpressure threshold, Neonate (mmHg)	150	165		
BUTTONS				
BP Determination Initiated				
"E80" displayed on SYSTOLIC display				
Audible alarm can be silenced				
"Silenced" LEDs flash				
Overpressure alarm can be cleared				
Alarm button is functioning				
DISPLAY				
All 7-Segment LEDs Light Correct Color				
All Discrete LEDs Light, Correct Color				
EXTERNAL DC DETECTION				
Charging indicator LED illuminated				
BP DETERMINATION				
Systolic reading (mmHg)				
Diastolic reading (mmHg)				
MAP reading (mmHg)				
Heart rate reading (bpm)				
Systolic reading (mmHg)				
Diastolic reading (mmHg)				
MAP reading (mmHg)				

Description	Min	Max	Actual	Pass-Fail-N/A
Heart rate reading (bpm)				
Systolic reading (mmHg)				
Diastolic reading (mmHg)				
MAP reading (mmHg)				
Heart rate reading (bpm)				
BP OVERPRESSURE				
"E80" displayed on SYSTOLIC display				
Pump will not start				
Overpressure alarm can be cleared				
TEMPERATURE TEST				
Temperature reading at 80.2° F	79.9° F	80.5° F		
Temperature reading at 98.6° F	98.4° F	98.8° F		
Temperature reading at 107.8° F	107.5° F	108.1° F		
SPO_2				
Pulse Value Displayed				
Saturation Value Displayed				
Signal Strength Bar				
"E23" displayed on SpO_2 display				
Alarm is silenced, error display remains				
Pulse Value				
Saturation Value Displayed				
Signal Strength Bar				
PRINTER TEST				
Printout is generated cleanly				
Temp Circuit Leakage Current (µA)		50		
SpO_2 Circuit Leakage Current (µA)		150		

5 Troubleshooting

For your notes

Alarm Code Interpretation

If any other alarms appear that are not listed in the paragraphs that follow, record the error message and report the failure to Customer Support. Refer to the operation manual for information about patient alarms and general procedural alarms.

System Failures

When a system failure is encountered, the error code is displayed on the screen for five seconds and the system enters failsafe mode. The error code is logged in the history log.

General system error codes are listed below. If any other SY or similar code appears, report it to Customer Support.

Alarm Conditions and Error Codes

When responding to a monitor alarm, always CHECK THE PATIENT FIRST and then check the Monitor, cuff, hose and sensors. Press SILENCE to reset patient alarm conditions.

Error Log

You can view and print an error log that stores up to 40 error code entries. The log is a "rolling" list that—once 40 entries are stored—deletes the oldest entry in order to add the most recent entry. The error log is saved until the monitor experiences a memory loss, then all entries are deleted.

NOTE: The error log feature is available in software revision RAI and subsequent revisions. Refer to Section 3, "Configuration Mode Settings" for information on how to determine the software revision of your monitor.

Procedure to View and Print Error Code History Log:

1. Enter the Advanced Configuration Mode (ACF) by holding down the **Minus** (-) and **Menu** buttons while powering up the monitor (pressing the **On/Off** button).
2. The monitor briefly displays the software revision, then displays ACF in the **Systolic** window.
3. The monitor is now in Advanced Configuration Mode
4. To view the error log use the **History** button to step through the log in reverse order of when the error occurred (oldest appears first).
5. The **Systolic** window shows the Year the error occurred.
6. The **Diastolic** window shows the Day the error occurred.
7. The **MAP** window shows the Month the error occurred.

8. The **SPO2** window shows the Time the error occurred.
9. The **Pulse Rate** window shows the error code that occurred at the recorded time.
10. To print the error log, press the **Print** button while viewing the log.

Error Code or Problem	Source	Definition	Can be Silenced?	Probable Source
Display blank, high pitch alarm	System	Failsafe error	No	Mains PWA issue
930	SPO2	No status from module for 30 ±10 sec. Fatal error reported by module	No	Check cable and sensor Parameter turned on - no hardware installed in unit
940	Temp	TEMP data samples less than 45 in 5 sec while idle	No	Incorrect or failed temperature probe
950	NIBP	NIBP pump on during idle or over current detected	No	Pneumatic assembly failure
951	NIBP	NIBP valve stuck closed during cuff typing	No	Pneumatic assembly failure
952	NIBP	NIBP PT2 higher than 150 for greater than 15 seconds while idle	No	Pneumatic assembly failure
970	Printer	Time base failure	No	Mains PWA issue
971	System	RAM test failure	No	Mains PWA issue
972	System	ROM checksum failure	No	Mains PWA issue
973	System	Secondary SPI communication error during initialization	No	Mains PWA issue
974	System	Calibration data invalid on initialization or unit never calibrated	No	Calibrate unit Mains PWA issue
975	System	Calibration data storage exhausted while saving data in CAL Mode	No	Return to depot for software installation
E00	System	Memory lost	Yes	Usually noted after changing batteries. User settings and date/ time revert to default settings.
E10	Printer	No paper in printer	Yes	No paper in printer Printer problem
E11	Printer	Printer too hot	Yes	Printer problem
E12	Battery	Battery to low to print	Yes	Charge battery Replace battery

Error Code or Problem	Source	Definition	Can be Silenced?	Probable Source
E13	Battery	Battery too low to operate the unit	No	Charge battery External DC source failed Replace battery
E21	SPO2	Failed SPO2 sensor		Replace SPO2 sensor
E23	SPO2	SPO2 Sensor off finger	Yes	Reposition SPO2 sensor
E25	SPO2	SPO2 No signal	Yes	Reposition SPO2 sensor
E61	Temp	Temp probe failure	No	Replace temperature probe
E63	Temp	Probe disconnected or wrong type	Yes	Check for correct probe
E66	Temp	Temperature probe too hot	No	Replace probe
E80	NIBP	Overpressure	Yes	Check for pinched or occluded internal tubing
E82	NIBP	Excess air in cuff	Yes	Wrong cuff type Failed valve on pneumatics assembly
E83	NIBP	NIBP inflation time out	Yes	Leak in cuff or o-ring in hose Internal leak in tubing or pneumatic valve Pump not turning on
E84	NIBP	NIBP total time out	Yes	Pneumatic assembly failure
E85	NIBP	NIBP level time out	Yes	Cuff placement on patient Minor leak in cuff Pneumatic assembly failure
E89	NIBP	NIBP no pulse detected	Yes	Cuff placement on patient

*****Acknowledging an alarm by pressing the Silence button, cancels the alarm.
** Call Technical Support for definitions and instructions.

6 Parts List, Drawings, and Replacement

For your notes

Ordering Parts

This section of the manual provides parts lists for the ProCare Monitor. Parts lists should be used in conjunction with the other chapters of this manual.

GE makes every effort possible to provide the most up-to-date reference documentation for your equipment. However, in special cases involving field-installed upgrades, the revision level of a diagram or parts list in this manual may not reflect the revision level of your unit's subassemblies. When discrepancies are found, contact your GE Medical Systems *Information Technologies* Service Representative.

NOTE: Fab drawings are not contained in this manual.

Service Parts

Compatible Parts

Part	Part Number
DINAMAP ProCare Monitor Operations Manual-English	2009360-001
DINAMAP ProCare Monitor Service Manual	2009381-001
Battery	633178CR
Universal Power Supply	2018859-001
Power Cord (US, Japan)	316579
Power Cord (Italy)	316599
Power Cord (France, Germany, Spain, Poland, Hungary, Russia)	316600
Power Cord (UK)	316601
Power Cord (Australia)	316679
Power Cord (China)	2007813-001
Printer Paper (box of 10)	089100
ProCare Roll Stand Assembly	2033297-001
Wall Mounting Option	CR-0008-01
Isolated Remote Alarm	487208CR

Part	Part Number
BP:	
Air Hose 12-ft Adult/Pediatric, Screw Connector	107365
Air Hose 24-ft Adult/Pediatric, Screw Connector	107366
Air Hose 12 ft Neonatal	107368
SENSA-CUF® 2-Tube Screw Connector, Infant	2458
SENSA-CUF® 2-Tube Screw Connector, Child	2460
SENSA-CUF® 2-Tube Screw Connector, Sm. Adult	2462
SENSA-CUF® 2-Tube Screw Connector, Adult	2464
SENSA-CUF® 2-Tube Screw Connector, Lg. Adult	2466
SENSA-CUF® 2-Tube Screw Connector, Thigh	2468
CUFF ASSORTMENT PACKS:	
CLASSIC-CUF® Assortment Pack Includes: 1 each: Infant, Child, Small Adult, Adult, Large Adult, Thigh Cuff	2692
CLASSIC-CUF® Assortment Pack, Neonate Includes: 2 Neo #1, 3 Neo #2, 5 Neo #3, 5 Neo #4, 5 Neo #5	2693
SOFT-CUF® Assortment Packs Includes: 1 Infant, 1 Child, 2 Small Adult, 2 Adult, 2 Large Adult, 1 Thigh, 1 Adult Long Cuff	002695
SOFT-CUF® Assortment, Neonate Includes: 2 Neo #1, 3 Neo #2, 5 Neo #3, 5 Neo #4, 5 Neo #5	2694
DURA-CUF® Assortment Pack Includes: 1 each: Infant, Child, Small Adult, Adult, Large Adult, Thigh Cuff	002699
DURA-CUF® Assortment Pack, Adult Includes: 1 Small Adult, 2 Adult, 1 Large Adult, 1 Large Adult Long, 1 Adult Long Cuff	002698
DURA-CUF® Assortment Pack, Child Includes: 2 Infant, 3 Child, and 1 Small Adult Cuff	002697
SENSA-CUF® Assortment Pack: Includes: 1 each: Small Adult, Adult, Large Adult	2494
Additional Blood Pressure Cuff Codes are available through: www.gehealthcare.com	
TEMPERATURE:	
IVAC* Turbo Temp Oral Temperature Probe, Long Cord	2008774-001
IVAC* Turbo Temp Rectal Temperature Probe, Long Cord	2008775-001
IVAC* Temperature Probe Covers/Case	088015

Part	Part Number
SPO_2:	
NELLCOR**:	
Pulse Oximeter Cable DOC-10	2008773-001
DuraSensor Adult Oxygen Sensor	DS100A
Masimo***:	
Adult Reusable Sensor, LNOP NR-195	2008278-001
Pulse Oximeter Cable (PC08)	2009743-001
*IVAC is a trademark of Alaris Medical Systems. **NELLCOR is a trademark of Nellcor Puritan Bennett. ***Masimo is a trademark of Masimo Corporation.	

Field-Replaceable Units (FRUs)

WARNING
REPAIR TO THE FRU LEVEL - Field repairs are recommended to the field replaceable unit (FRU) only. Attempting a field repair on a PCB or a factory sealed component or assembly could jeopardize the safe and effective operation of the monitor.

FRU List

The following table offers details of each of the corresponding bubble numbers that appear on the exploded engineering-assembly drawing (drawing is located after this table).

NOTE: FRU numbers are subject to change.

Bubble Number	Part Number	Description
1	2007970-001	NIBP CONNECTOR
2	2009910-001	ASSY MAIN PWA PROCARE FRU
3	2009911-001	ASSY MAIN PWA-AUSC PROCARE FRU
4	2009912-001	ASSY UI PWA PROCARE FRU
5	2009915-001	PLASTIC KIT, PROCARE W/PRINTER
6	2009915-002	PLASTIC KIT, PROCARE W/OUT PRINTER
7	2009915-003	HANDLE FRU, 3 PER PACK
8	2030094-001	ASSY NELLCOR NELL-3 MODULE FRU
9	2009913-001	ASSY NELLCOR MP506 MODULE FRU
10	2009914-001	ASSY MASIMO MS5 MODULE FRU
12	2009916-001	SCREWS & HARDWARE KIT PROCARE FRU
13	2009917-001	KIT, PRINTER PROCARE FRU
14	2009918-001	KIT, TEMP PROCARE FRU
15	2009919-001	KIT, PRINTER DOOR PROCARE FRU
16	2009920-001	PUMP PROCARE FRU
17	2009921-001	KIT, DUMP VALVE PROCARE FRU
18	2009922-001	KIT, SPEAKER PROCARE FRU
19	2009923-001	KIT, INTERNAL HOST COMMS CABLE PROCARE FRU
20	2010429-001	KIT, FRU, SIDE LABEL AND FASCIA, ENGLISH, DPC400, PRINT

Bubble Number	Part Number	Description
20	2010478-001	KIT, FRU, LABEL, ENGLISH, DPC300, PRINT
20	2010479-001	KIT, FRU, LABEL, ENGLISH, DPC200, PRINT
20	2010480-001	KIT, FRU, LABEL, ENGLISH, DPC100, PRINT
21	2011645-001	FRU PROCARE ENGLISH KEYPAD LABEL SET, 100-400
20	2008329-001	PLASTIC DISPLAY COVER 400 ENGLISH 2010371-001 PLASTIC DISPLAY COVER, DPC200, NORWEGIAN
20	2008330-001	PLASTIC DISPLAY COVER 300 ENGLISH 2010372-001 PLASTIC DISPLAY COVER, DPC100, NORWEGIAN
20	2008331-001	PLASTIC DISPLAY COVER 200 ENGLISH 2010381-001 PLASTIC DISPLAY COVER, DPC400, FINNISH
20	2008332-001	PLASTIC DISPLAY COVER 100 ENGLISH 2010382-001 PLASTIC DISPLAY COVER, DPC 300, FINNISH
20	2008498-001	PLASTIC DISPLAY COVER 400 FRENCH 2010383-001 PLASTIC DISPLAY COVER, DPC 200, FINNISH
20	2008499-001	PLASTIC DISPLAY COVER 300 FRENCH 2010384-001 PLASTIC DISPLAY COVER, DPC100, FINNISH
20	2008500-001	PLASTIC DISPLAY COVER 200 FRENCH 2010385-001 PLASTIC DISPLAY COVER, DPC400, PORTUGUESE
20	2008501-001	PLASTIC DISPLAY COVER 100 FRENCH 2010386-001 PLASTIC DISPLAY COVER, DPC300, PORTUGUESE
20	2008502-001	PLASTIC DISPLAY COVER 400 GERMAN 2010387-001 PLASTIC DISPLAY COVER, DPC200, PORTUGUESE
20	2008503-001	PLASTIC DISPLAY COVER 300 GERMAN 2010388-001 PLASTIC DISPLAY COVER, DPC100, PORTUGUESE
20	2008504-001	PLASTIC DISPLAY COVER 200 GERMAN 2010390-001 PLASTIC DISPLAY COVER, DPC400, RUSSIAN
20	2008505-001	PLASTIC DISPLAY COVER 100 GERMAN 2010391-001 PLASTIC DISPLAY COVER, DPC300, RUSSIAN
20	2008506-001	PLASTIC DISPLAY COVER 400 SPANISH 2010392-001 PLASTIC DISPLAY COVER, DPC200, RUSSIAN
20	2008507-001	PLASTIC DISPLAY COVER 300 SPANISH 2010393-001 PLASTIC DISPLAY COVER, DPC100, RUSSIAN
20	2008508-001	PLASTIC DISPLAY COVER 200 SPANISH 2010399-001 PLASTIC DISPLAY COVER, DPC400, HUNGARIAN
20	2008509-001	PLASTIC DISPLAY COVER 100 SPANISH 2010400-001 PLASTIC DISPLAY COVER, DPC300, HUNGARIAN

Bubble Number	Part Number	Description
20	2008510-001	PLASTIC DISPLAY COVER 400 ITALIAN 2010401-001 PLASTIC DISPLAY COVER, DPC200, HUNGARIAN
20	2008511-001	PLASTIC DISPLAY COVER 300 ITALIAN 2010402-001 PLASTIC DISPLAY COVER, DPC100, HUNGARIAN
20	2008512-001	PLASTIC DISPLAY COVER 200 ITALIAN 2010403-001 PLASTIC DISPLAY COVER, DPC400, CZECH
20	2008513-001	PLASTIC DISPLAY COVER 100 ITALIAN 2010404-001 PLASTIC DISPLAY COVER, DPC300, CZECH
20	2008514-001	PLASTIC DISPLAY COVER 400 SWEDISH 2010405-001 PLASTIC DISPLAY COVER, DPC200, CZECH
20	2008515-001	PLASTIC DISPLAY COVER 300 SWEDISH 2010406-001 PLASTIC DISPLAY COVER, DPC100, CZECH
20	2008516-001	PLASTIC DISPLAY COVER 200 SWEDISH 2010407-001 PLASTIC DISPLAY COVER, DPC400, SLOVAK
20	2008517-001	PLASTIC DISPLAY COVER 100 SWEDISH 2010408-001 PLASTIC DISPLAY COVER, DPC300, SLOVAK
20	2008518-001	PLASTIC DISPLAY COVER 400 DUTCH 2010409-001 PLASTIC DISPLAY COVER, DPC200, SLOVAK
20	2008519-001	PLASTIC DISPLAY COVER 300 DUTCH 2010410-001 PLASTIC DISPLAY COVER, DPC100, SLOVAK
20	2008520-001	PLASTIC DISPLAY COVER 200 DUTCH 2010411-001 PLASTIC DISPLAY COVER, DPC400, POLISH
20	2008521-001	PLASTIC DISPLAY COVER 100 DUTCH 2010412-001 PLASTIC DISPLAY COVER, DPC300, POLISH
20	2009481-001	LABEL, DISPLAY COVERS, CHINESE, 400 2010413-001 PLASTIC DISPLAY COVER, DPC200, POLISH
20	2009482-001	LABEL, DISPLAY COVERS, CHINESE, 300 2010414-001 PLASTIC DISPLAY COVER, DPC100, POLISH
20	2009483-001	LABEL, DISPLAY COVERS, CHINESE, 200 2010349-001 PLASTIC DISPLAY COVER, DPC 400,GREEK
20	2009484-001	LABEL, DISPLAY COVERS, CHINESE, 100 2010350-001 PLASTIC DISPLAY COVER, DPC300, GREEK
20	2010365-001	PLASTIC DISPLAY COVER, DPC400, DANISH 2010351-001 PLASTIC DISPLAY COVER, DPC 200,GREEK
20	2010366-001	PLASTIC DISPLAY COVER, DPC300, DANISH 2010352-001 PLASTIC DISPLAY COVER, DPC100, GREEK
20	2010367-001	PLASTIC DISPLAY COVER, DPC200, DANISH 2010353-001 PLASTIC DISPLAY COVER, DPC 400,JAPANESE

Bubble Number	Part Number	Description
20	2010368-001	PLASTIC DISPLAY COVER, DPC100, DANISH 2010354-001 PLASTIC DISPLAY COVER, DPC 300, JAPANESE
20	2010369-001	PLASTIC DISPLAY COVER, DPC400, NORWEGIAN 2010355-001 PLASTIC DISPLAY COVER, DPC 200, JAPANESE
20	2010370-001	PLASTIC DISPLAY COVER, DPC300, NORWEGIAN 2010356-001 PLASTIC DISPLAY COVER, DPC 100, JAPANESE
20	2008333-001	LABEL FASCIA PRO CARE 400 ENGLISH 2009407-001 LABEL FASCIA, NORWEGIAN 200
20	2008334-001	LABEL FASCIA PRO CARE 300 ENGLISH 2009409-001 LABEL FASCIA, NORWEGIAN 100
20	2008335-001	LABEL FASCIA PRO CARE 200 ENGLISH 2009414-001 LABEL, FASCIA, PROCARE, FINNISH 400
20	2008336-001	LABEL FASCIA PRO CARE 100 ENGLISH 2009415-001 LABEL, FASCIA, PROCARE, FINNISH 300
20	2008405-001	LABEL FASCIA PRO CARE 400 FRENCH 2009416-001 LABEL, FASCIA, PROCARE, FINNISH 200
20	2008406-001	LABEL FASCIA PRO CARE 300 FRENCH 2009417-001 LABEL, FASCIA, PROCARE, FINNISH 100
20	2008407-001	LABEL FASCIA PRO CARE 200 FRENCH 2009418-001 LABEL, FASCIA, PORTUGUESE 400
20	2008408-001	LABEL FASCIA PRO CARE 100 FRENCH 2009419-001 LABEL, FASCIA, PORTUGUESE 300
20	2008409-001	LABEL FASCIA PRO CARE 400 GERMAN 2009420-001 LABEL, FASCIA, PORTUGUESE 200
20	2008410-001	LABEL FASCIA PRO CARE 300 GERMAN 2009421-001 LABEL, FASCIA, PORTUGUESE 100
20	2008411-001	LABEL FASCIA PRO CARE 200 GERMAN 2009422-001 LABEL, FASCIA, PROCARE, RUSSIAN 400
20	2008412-001	LABEL FASCIA PRO CARE 100 GERMAN 2009423-001 LABEL, FASCIA, PROCARE, RUSSIAN 300
20	2008413-001	LABEL FASCIA PROCARE 400 SPANISH 2009424-001 LABEL, FASCIA, PROCARE, RUSSIAN 200
20	2008414-001	LABEL FASCIA PROCARE 300 SPANISH 2009425-001 LABEL, FASCIA, PROCARE, RUSSIAN 100
20	2008415-001	LABEL FASCIA PROCARE 200 SPANISH 2009426-001 LABEL, FASCIA, HUNGARIAN 400
20	2008416-001	LABEL FASCIA PROCARE 100 SPANISH 2009427-001 LABEL, FASCIA, HUNGARIAN 300
20	2008417-001	LABEL FASCIA PROCARE 400 ITALIAN 2009428-001 LABEL, FASCIA, HUNGARIAN 200
20	2008418-001	LABEL FASCIA PRO CARE 300 ITALIAN 2009429-001 LABEL, FASCIA, HUNGARIAN 100
20	2008419-001	LABEL FASCIA PRO CARE 200 ITALIAN 2009430-001 LABEL, FASCIA, CZECH 400
20	2008420-001	LABEL FASCIA PRO CARE 100 ITALIAN 2009431-001 LABEL, FASCIA, CZECH 300
20	2008421-001	LABEL, FASCIA, PRO CARE 400, SWEDISH 2009432-001 LABEL, FASCIA, CZECH 200

Bubble Number	Part Number	Description
20	2008422-001	LABEL, FASCIA, PRO CARE 300, SWEDISH 2009433-001 LABEL, FASCIA, CZECH 100
20	2008423-001	LABEL, FASCIA, PRO CARE 200, SWEDISH 2009434-001 LABEL, FASCIA, SLOVAK 400
20	2008424-001	LABEL, FASCIA, PRO CARE 100, SWEDISH 2009435-001 LABEL, FASCIA, SLOVAK 300
20	2008425-001	LABEL FASCIA PRO CARE 400 DUTCH 2009436-001 LABEL, FASCIA, SLOVAK 200
20	2008426-001	LABEL FASCIA PRO CARE 300 DUTCH 2009438-001 LABEL, FASCIA, SLOVAK 100
20	2008427-001	LABEL FASCIA PRO CARE 200 DUTCH 2009439-001 LABEL,FASCIA, POLISH 400
20	2008428-001	LABEL FASCIA PRO CARE 100 DUTCH 2009440-001 LABEL,FASCIA, POLISH 300
20	2009390-001	LABEL FASCIA, CHINESE 2009441-001 LABEL,FASCIA, POLISH 200
20	2009392-001	LABEL FASCIA, CHINESE 300 2009442-001 LABEL,FASCIA, POLISH 100
20	2009393-001	LABEL FASCIA, CHINESE 200 2010423-001 LABEL,FASCIA,PROCARE400,GREEK
20	2009394-001	LABEL FASCIA, CHINESE 100 2010424-001 LABEL,FASCIA,PROCARE300,GREEK
20	2011813-001	LABEL, FASCIA, PROCARE, DANISH 400 2010425-001 LABEL,FASCIA,PROCARE200,GREEK
20	2009401-001	LABEL FASCIA, DANISH 300 2010426-001 LABEL,FASCIA,PROCARE100,GREEK
20	2009402-001	LABEL FASCIA, DANISH 200 2009396-001 LABEL FASCIA, JAPANESE 400
20	2009403-001	LABEL FASCIA, DANISH 100 2009397-001 LABEL FASCIA, JAPANESE 300
20	2009404-001	LABEL FASCIA, NORWEGIAN 400 2009398-001 LABEL FASCIA, JAPANESE 200
20	2009406-001	LABEL FASCIA, NORWEGIAN 300 2009399-001 LABEL FASCIA, JAPANESE 100
21	2007843-001	LABEL SET, KEYPAD ENGLISH 400 PRINT
21	2008591-001	LABEL SET, KEYPAD ENGLISH 300 PRINT
21	2008592-001	LABEL SET, KEYPAD ENGLISH 200 PRINTER
21	2008593-001	LABEL SET, KEYPAD ENGLISH 100 PRINTER
21	2008797-001	LABEL SET, KEYPAD DPC400 FRENCH PRINTER
21	2008798-001	LABEL SET, KEYPAD DPC300 FRENCH PRINTER
21	2008799-001	LABEL SET, KEYPAD DPC200 FRENCH PRINTER
21	2008800-001	LABEL SET, KEYPAD DPC100 FRENCH PRINTER
21	2008801-001	LABEL SET, KEYPAD DPC400 GERMAN PRINTER
21	2008802-001	LABEL SET, KEYPAD DPC300 GERMAN PRINTER
21	2008803-001	LABEL SET, KEYPAD DPC200 GERMAN PRINTER
21	2009812-001	LABEL SET, KEYPAD DPC100 GERMAN PRINTER
21	2008805-001	LABEL, KEYPAD DPC400 SPANISH PRINTER

Bubble Number	Part Number	Description
21	2008806-001	LABEL, KEYPAD DPC300 SPANISH PRINTER
21	2008807-001	LABEL, KEYPAD DPC200 SPANISH PRINTER
21	2008808-001	LABEL, KEYPAD DPC100 SPANISH PRINTER
21	2010815-001	LABEL SET, KEYPAD DPC400,ENGLISH,PRINT,AUSC
21	2010816-001	LABEL SET, KEYPAD,DPC300,ENGLISH,PRINT,AUSC
21	2010817-001	LABEL SET, KEYPAD,DPC200,ENGLISH,PRINT,AUSC
21	2010818-001	LABEL SET, KEYPAD,DPC100,ENGLISH,PRINT,AUSC
21	2010823-001	LABEL SET, KEYPAD,DPC400,FRENCH,PRINT,AUSC
21	2010824-001	LABEL SET, KEYPAD,DPC300,FRENCH,PRINT,AUSC
21	2010825-001	LABEL SET, KEYPAD,DPC200,FRENCH,PRINT,AUSC
21	2010826-001	LABEL SET, KEYPAD,DPC100,FRENCH,PRINT,AUSC
21	2010831-001	LABEL SET, KEYPAD,DPC400,GERMAN,PRINT,AUSC
21	2010832-001	LABEL SET, KEYPAD,DPC300,GERMAN,PRINT,AUSC
21	2010833-001	LABEL SET, KEYPAD,DPC200,GERMAN,PRINT,AUSC
21	2010834-001	LABEL SET, KEYPAD,DPC100,GERMAN,PRINT,AUSC
21	2008809-001	LABEL, KEYPAD DPC400 ITALIAN PRINTER
21	2008810-001	LABEL, KEYPAD DPC300 ITALIAN PRINTER
21	2008811-001	LABEL, KEYPAD DPC200 ITALIAN PRINTER
21	2008812-001	LABEL,KEYPAD, DPC100 ITALIAN PRINTER
21	2008813-001	LABEL, KEYPAD DPC400 SWEDISH PRINTER
21	2008814-001	LABEL, KEYPAD DPC300 SWEDISH PRINTER
21	2008815-001	LABEL, KEYPAD DPC200 SWEDISH PRINTER
21	2008816-001	LABEL, KEYPADDPC100 SWEDISH PRINTER
21	2008817-001	LABEL SET, KEYPAD, DPC400, DUTCH, PRINTER
21	2008818-001	LABEL SE, KEYPADT, DPC300, DUTCH, PRINTER
21	2008819-001	LABEL SET, KEYPAD, DPC200, DUTCH, PRINTER
21	2008820-001	LABEL SET, KEYPAD, DPC100, DUTCH, PRINTER
21	2009129-001	LABEL, KEYPAD,DPC400 CHINESE PRINTER
21	2009130-001	LABEL, KEYPAD DPC300 CHINESE PRINTER
21	2009137-001	LABEL, KEYPAD DPC200 CHINESE PRINTER

Bubble Number	Part Number	Description
21	2009138-001	LABEL, KEYPAD DPC100 CHINESE PRINTER
21	2009147-001	LABEL, KEYPAD DPC400, DANISH, PRINTER
21	2009148-001	LABEL, KEYPAD, DPC300, DANISH, PRINTER
21	2009172-001	LABEL, KEYPAD, DPC100, PORTUGUESE, PRINTER
21	2009173-001	LABEL, KEYPAD, DPC400, RUSSIAN, PRINTER
21	2009175-001	LABEL, KEYPAD, DPC300, RUSSIAN, PRINTER
21	2009176-001	LABEL, KEYPAD, DPC200, RUSSIAN, PRINTER
21	2009177-001	LABEL, KEYPAD, DPC100, RUSSIAN, PRINTER
21	2009178-001	LABEL, KEYPAD, DPC400, HUNGARIAN, PRINTER
21	2009179-001	LABEL, KEYPAD, DPC300, HUNGARIAN, PRINTER
21	2009180-001	LABEL, KEYPAD, DPC200, HUNGARIAN, PRINTER
21	2009181-001	LABEL, KEYPAD, DPC100, HUNGARIAN, PRINTER
21	2009182-001	LABEL, KEYPAD DPC400, CZECH, PRINTER
21	2009183-001	LABEL, KEYPAD, DPC300, CZECH, PRINTER
21	2009184-001	LABEL, KEYPAD, DPC200, CZECH, PRINTER
21	2009185-001	LABEL, KEYPAD, DPC100, CZECH, PRINTER
21	2009186-001	LABEL, KEYPAD, DPC400, SLOVAK, PRINTER
21	2009187-001	LABEL, KEYPAD, DPC300, SLOVAK, PRINTER
21	2009188-001	LABEL, KEYPAD, DPC200, SLOVAK, PRINTER
21	2009189-001	LABEL, KEYPAD, DPC100, SLOVAK, PRINTER
21	2009190-001	LABEL, KEYPAD, DPC400, POLISH,PRINTER
21	2009191-001	LABEL, KEYPAD, DPC300, POLISH, PRINTER
21	2009192-001	LABEL, KEYPAD, DPC200, POLISH, PRINTER
21	2009193-001	LABEL, KEYPAD, DPC100, POLISH,PRINTER
21	2009143-001	LABEL SET, KEYPAD, DPC400, GREEK, PRINTER
21	2009144-001	LABEL SET, KEYPAD, DPC300, GREEK, PRINTER
21	2009145-001	LABEL SET, KEYPAD, DPC200, GREEK, PRINTER
21	2009146-001	LABEL SET, KEYPAD, DPC100, GREEK, PRINTER
21	2010733-001	LABEL,KEYPAD,DPC400,ENGLISH,PRINTERLESS
21	2010734-001	LABEL,KEYPAD,DPC300,ENGLISH,PRINTERLESS

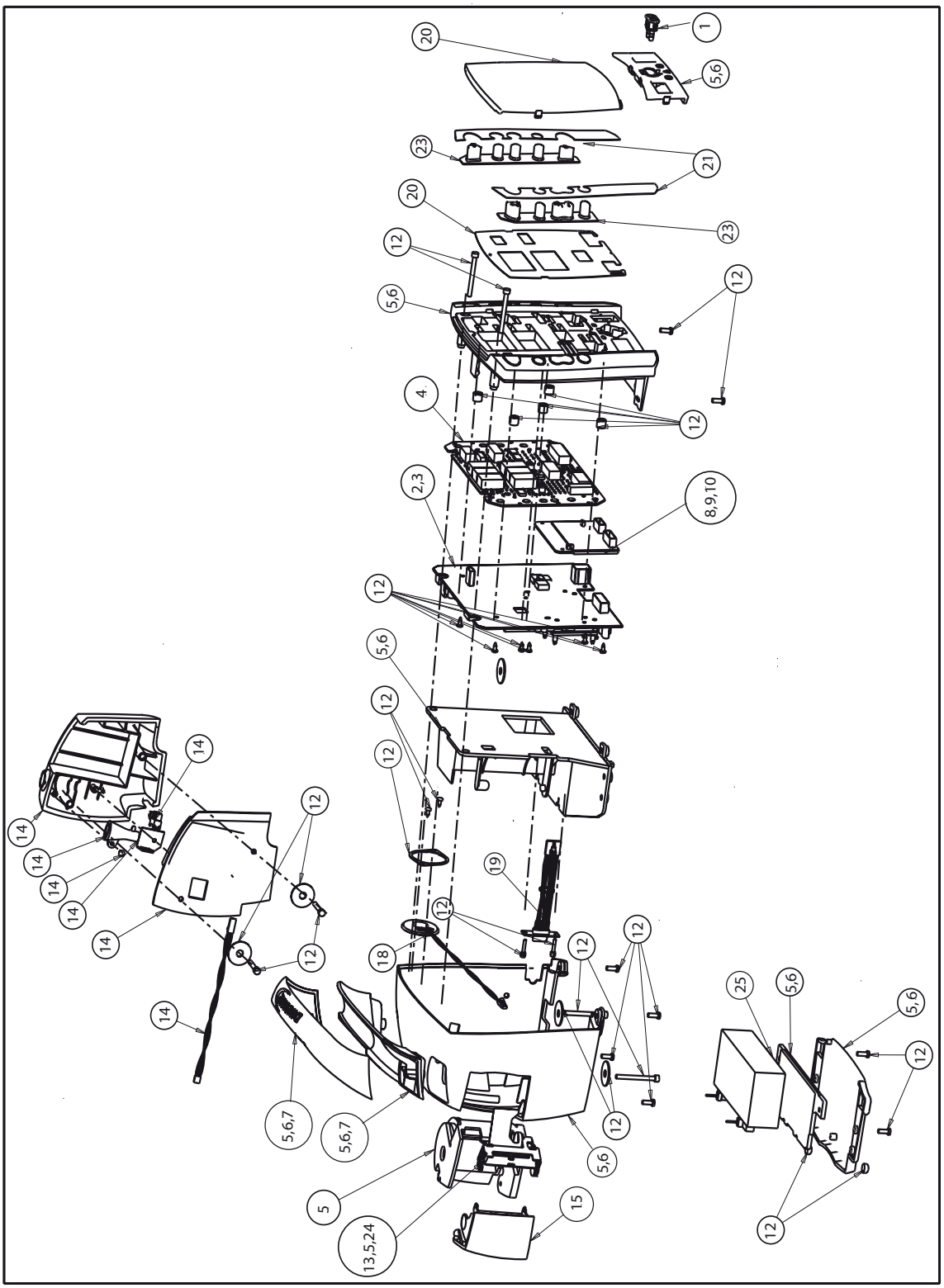
Bubble Number	Part Number	Description
21	2010735-001	LABEL,KEYPAD,DPC200,ENGLISH,PRINTERLESS
21	2010736-001	LABEL,KEYPAD,DPC100,ENGLISH,PRINTERLESS
21	2010737-001	LABEL,KEYPAD,DPC400,FRENCH,PRINTERLESS
21	2010738-001	LABEL,KEYPAD,DPC300,FRENCH,PRINTERLESS
21	2010739-001	LABEL,KEYPAD,DPC200,FRENCH,PRINTERLESS
21	2010740-001	LABEL,KEYPAD,DPC100,FRENCH,PRINTERLESS
21	2010741-001	LABEL,KEYPAD,DPC400,GERMAN,PRINERLESS
21	2010742-001	LABEL,KEYPAD,DPC300,GERMAN,PRINTERLESS
21	2010743-001	LABEL,KEYPAD,DPC200,GERMAN,PRINTERLESS
21	2010744-001	LABEL,KEYPAD,DPC100,GERMAN,PRINTERLESS
21	2010745-001	LABEL,KEYPAD,DPC400,SPANISH,PRINTERLESS
21	2010746-001	LABEL,KEYPAD,DPC300,SPANISH,PRINTERLESS
21	2010747-001	LABEL,KEYPAD,DPC200,SPANISH,PRINTERLESS
21	2010748-001	LABEL,KEYPAD,DPC100,SPANISH,PRINTERLESS
21	2010749-001	LABEL,KEYPAD,DPC400,ITALIAN,PRINTERLESS
21	2010750-001	LABEL,KEYPAD,DPC300,ITALIAN,PRINTERLESS
21	2010751-001	LABEL,KEYPAD,DPC200,ITALIAN,PRINTERLESS
21	2010752-001	LABEL,KEYPAD,DPC100,ITALIAN,PRINTERLESS
21	2010753-001	LABEL,KEYPAD,DPC400,SWEDISH,PRINTERLESS
21	2010767-001	LABEL,KEYPAD,DPC200,JAPANESE,PRINTERLESS
21	2010768-001	LABEL,KEYPAD,DPC100,JAPANESE,PRINTERLESS
21	2010770-001	LABEL,KEYPAD,DPC400,DANISH,PRINTERLESS
21	2010771-001	LABEL,KEYPAD,DPC300,DANISH,PRINTERLESS
21	2010772-001	LABEL,KEYPAD,DPC200,DANISH,PRINTERLESS
21	2010773-001	LABEL,KEYPAD,DPC100,DANISH,PRINTERLESS
21	2010774-001	LABEL,KEYPAD,DPC400,NORWEGIAN,PRINTRLESS
21	2010775-001	LABEL,KEYPAD,DPC300,NORWEGIAN,PRINTRLESS
21	2010776-001	LABEL,KEYPAD,DPC200,NORWEGIAN,PRINTRLESS
21	2010777-001	LABEL,KEYPAD,DPC100,NORWEGIAN,PRINTRLESS
21	2010782-001	LABEL,KEYPAD,DPC400,FINNISH,PRINTERLESS

Bubble Number	Part Number	Description
21	2010783-001	LABEL,KEYPAD,DPC300,FINNISH,PRINTERLESS
21	2010784-001	LABEL,KEYPAD,DPC200,FINNISH,PRINTERLESS
21	2010785-001	LABEL,KEYPAD,DPC100,FINNISH,PRINTERLESS
21	2010786-001	LABEL,KEYPAD,DPC400,PORTUGUESE,PRINTLESS
21	2010788-001	LABEL,KEYPAD,DPC300,PORTUGUESE,PRINTLESS
21	2010789-001	LABEL,KEYPAD,DPC200,PORTUGUESE,PRINTLESS
21	2010790-001	LABEL,KEYPAD,DPC100,PORTUGUESE,PRINTLESS
21	2010791-001	LABEL.KEYPAD,DPC400,RUSSIAN,PRINTERLESS
21	2010792-001	LABEL,KEYPAD,DPC300,RUSSIAN,PRINTERLESS
21	2010793-001	LABEL,KEYPAD,DPC200,RUSSIAN,PRINTERLESS
21	2010794-001	LABEL,KEYPAD,DPC100,RUSSIAN,PRINTERLESS
21	2010795-001	LABEL,KEYPAD,DPC400,HUNGARIAN,PRINTRLESS
21	2010796-001	LABEL,KEYPAD,DPC300,HUNGARIAN,PRINTRLESS
21	2010797-001	LABEL,KEYPAD,DPC200,HUNGARIAN,PRINTRLESS
21	2010798-001	LABEL,KEYPAD,DPC100,HUNGARIAN,PRINTRLESS
21	2010799-001	LABEL,KEYPAD,DPC400,CZECH,PRINTERLESS
21	2010800-001	LABEL,KEYPAD,DPC300,CZECH,PRINTERLESS
21	2010801-001	LABEL,KEYPAD,DPC200,CZECH,PRINTERLESS
21	2010802-001	LABEL,KEYPAD,DPC100,CZECH,PRINTERLESS
21	2010803-001	LABEL,KEYPAD,DPC400,SLOVAK,PRINTERLESS
21	2010804-001	LABEL,KEYPAD,DPC300,SLOVAK,PRINTERLESS
21	2010805-001	LABEL,KEYPAD,DPC200,SLOVAK,PRINTERLESS
21	2010806-001	LABEL,KEYPAD,DPC100,SLOVAK,PRINTERLESS
21	2010807-001	LABEL,KEYPAD,DPC400,POLISH,PRINTERLESS
21	2010808-001	LABEL,KEYPAD,DPC300,POLISH,PRINTERLESS
21	2010809-001	LABEL,KEYPAD,DPC200,POLISH,PRINTERLESS
21	2010810-001	LABEL,KEYPAD,DPC100,POLISH,PRINTERLESS
21	2010811-001	LABEL,KEYPAD,DPC400,GREEK,PRINTERLESS
21	2010812-001	LABEL,KEYPAD,DPC300,GREEK,PRINTERLESS
21	2010813-001	LABEL,KEYPAD,DPC200,GREEK,PRINTERLESS

Bubble Number	Part Number	Description
21	2010814-001	LABEL,KEYPAD,DPC100,GREEK,PRINTERLESS
21	2010819-001	LABEL,KEYPAD,DPC400,ENGLISH,AUSC,PRNTLSS
21	2010820-001	LABEL,KEYPAD,DPC300,ENGLISH,AUSC,PRNTLSS
21	2010821-001	LABEL,KEYPAD,DPC200,ENGLISH,AUSC,PRNTLSS
21	2010822-001	LABEL,KEYPAD,DPC100,ENGLISH,AUSC,PRNTLSS
22	2011830-001	KIT, FRU HELP CARD GUIDES ENGLISH
23	2018389-001	KIT, KEYPADS LEFT & RIGHT PROCARE FRU
24	2020006-001	PRINTER ROLLER
25	633178CR	BATTERY, LEAD-ACID, 6-VOLT, 3.0 AH

FRU Main Reference Guide Drawing

For quick reference use the following FRU Main Reference Guide drawing.



Assembly/Disassembly of FRUs

Monitor Disassembly Procedure

The following procedure is sequential (i.e., you must remove the battery and rear case to remove the printer, etc.

Battery

1. Remove 4 screws securing the instruction cards.

2. Remove the battery compartment door and adhesive pad.
3. The battery can now be removed.

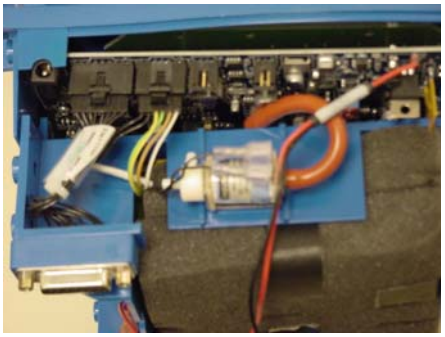
Rear Case

1. Remove remaining four screws from the bottom of the monitor.
2. Set monitor upright.

3. Carefully remove the front faceplate.

4. Remove 2 screws behind black overlay.

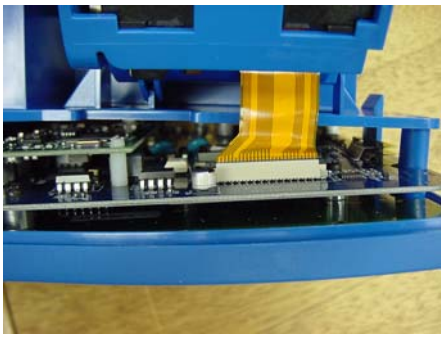
5. Set monitor on its face and open the printer door.
6. Carefully remove the rear case.
7. Unplug speaker cable from circuit board.
8. Unplug rear case cable.



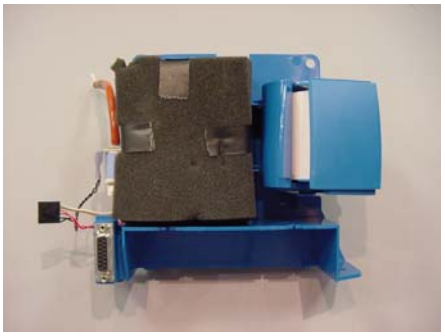
Printer

1. Unplug air hose from valve and 2 elbow joints.
2. Remove 3 cable assemblies.

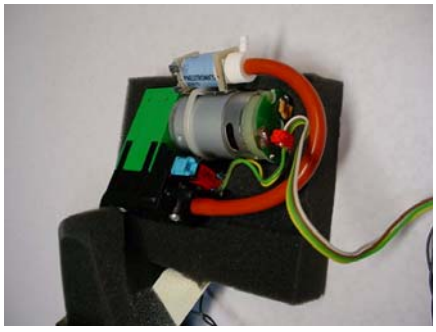
3. Moves aside battery cables.
4. Locate and release retention tab and slide back sub chassis.
5. Lift the 2 black tabs and remove printer cable.



6. Remove printer assembly.
7. Remove sub-chassis and set aside.



8. Remove pneumatic assembly from sub-chassis.



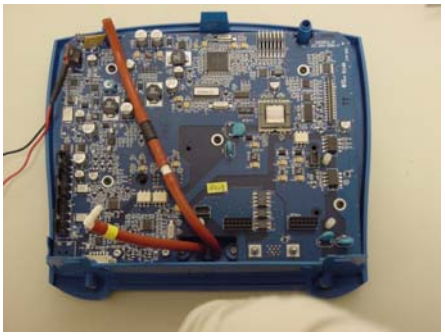
SpO_2 Board

1. Remove hex nuts near SPO2 board.

2. Turn monitor over and remove 2 SPO2 connector screws.
3. Turn monitor on its face.
4. Using needle nose pliers squeeze nylon retention tabs and remove SPO2 board.

Main Board

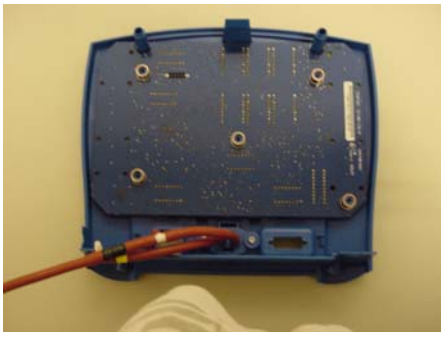
1. Remove 5 phillips screws.



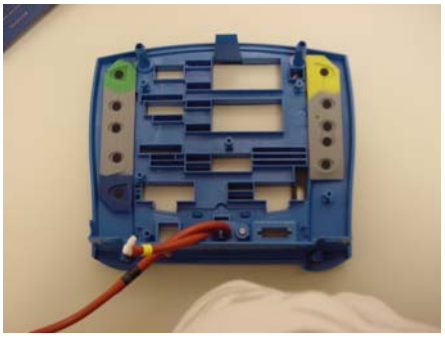
2. Remove 2 torques head screws.
3. Unplug tubing from main bd.

Display Board

1. Carefully lift the Main board away from the Display board.



2. Collect the 5 spacers used to align the Main and Display Boards.
3. Lift the display board away from the front panel.



4. The monitor is now completely disassembled.
5. Reverse the above sequence to reassemble the monitor.
6. Be careful not to pinch any cables or tubing during reassembly.

NOTE: Updated Instructions may be included in your replacement parts kit, always review all material included in your kit.

A Technical Specifications

For your notes

Specifications

Mechanical

Dimensions	Height: 9.7 in (24.7 cm) Width: 8.6 in (21.9 cm) without Temperature 10.0 in (25.4 cm) with Temperature Depth: 5.3 in (13.5 cm)
Weight, Including Battery	5.68 lb (2.58 kg)
Mountings	Self-supporting on rubber feet
Portability	Carried by handle
Classification Information	Mode of operation: continuous Degree of protection against harmful ingress of water: Drip-proof IPX1

Power Requirements

Power Converter US	P/N: 2018859-001 Protection against electrical shock: Class II AC input: 100-250 VAC/50-60 Hz 12W DC output voltage: 12VDC at 1.0A The AC mains power adapter contains a nonresettable and nonreplaceable fuse.
Monitor	Protection against electricalshock: Internally powered or Class II when powered from specified external power supply. DC input voltage: 12 VDC, supplied from a source conforming to IEC 60601-1. Fuses: The Monitor contains four fuses. The fuses are auto-resettable and mounted within the Monitor. The fuses protect the low voltage DC input, the battery, the remote alarm output, and the +5 V output on the host port connector. Battery: 6 volt, 3.3 amp-hours protected by internal auto-resetting fuse and thermal protection. Minimum operation time: 5 hrs (5 min cycle with adult cuff at 25 °C, SpO_2 active at 60 bpm, Temp in monitor mode) from full charge. Time for full recharge: Approx. 5 hrs from full discharge when the Monitor is switched off and approx. 8 hrs when the Monitor is switched on.

Environmental

Operating Temperature	+ 5 °C to + 40 °C (+ 41 °F to + 104 °F)
Operating Atmospheric Pressure	700 hPa to 1060 hPa
Storage Temperature	– 20 °C to + 50 °C (– 4 °F to + 122 °F)
Storage/Transportation Atmospheric Pressure	500 hPa to 1060 hPa
Humidity Range	5% to 95% noncondensing
Radio Frequency	Complies with IEC Publication 60601-1-2 Medical Electrical Equipment, Electromagnetic Compatibility Requirements and Tests and CISPR 11 (Group 1, Class B) for radiated and conducted emissions.

BP

Cuff Pressure Range (Normal operating range)	0 to 290 mmHg (adult/ped) 0 to 140 mmHg (neonate)
Blood Pressure Accuracy	Meets ANSI/AAMI standard SP-10 (mean error ≤5 mmHg, standard deviation ≤8 mmHg). Auscultatory: BHS protocol Grade A/A; ESH protocol requirements passed
Maximum Determination Time	120 s (adult/ped) 85 s (neonate)
Overpressure Cutoff	300 to 330 mmHg (adult/ped) 150 to 165 mmHg (neonate)
Pulse Rate Range	30 to 200 beats/min (adult/ped) 30 to 220 beats/min (neonate)
Pulse Rate Accuracy	± 3.5%

Factory Default Settings

Systolic Limits (mmHg)	HIGH: 200 LOW: 80
Diastolic Limits (mmHg)	HIGH: 120 LOW: 30
Inflation Pressure*	160 mmHg (adult/ped) 110 mmHg (neonate)
Cycle button	15

*****Default inflation pressure can be changed in Config Mode. Refer to the **Getting Started** section of operation manual.

All DINAMAP® Monitor regulatory and accuracy studies have been performed using CRITIKON® Blood Pressure Cuffs. Use only CRITIKON® Blood Pressure Cuffs. The size, shape, and bladder characteristics can affect the performance of the instrument. Inaccurate readings may occur unless CRITIKON® Blood Pressure Cuffs are used.

Critikon US Patents

4,360,029; 4,501,280; 4,546,775; 4,638,810; 5,052,397; 4,349,034; 4,543,962; 4,627,440; 4,754,761; 5,170,795

European Patents

EP122123, EP205805, EP207807

Nellcor SpO_2

Measurement Range

SpO_2	1 to 100%
Pulse Rate	20 to 250 beats/min

Accuracy and Motion Tolerance

Saturation

Adults*	70 to 100% ±2 digits
Neonate*	70 to 100% ±3 digits
Low Perfusion**	70 to 100% ±2 digits 0 to 69% unspecified

Pulse Rate

Adult and Neonate	20 to 250 beats/min ±3 digits
Low Perfusion**	20 to 250 beats/min ±3 digits

*Adult specifications are shown for OxiMax® MAX-A and MAX-N sensors with the N-600. Neonate specifications are shown for OxiMax® MAX-N with the N-600. Saturation accuracy will vary by sensor type.

**Applicability: OxiMax® MAX-A, MAX-AL, MAX-P, MAX-I, and MAX-N sensors.

NELLCOR® Sensor Accuracy

NOTE: All NELLCOR® sensors must be used with the NELLCOR® DOC-10 cable; the SCP-10 cable is not compatible with the ProCare Monitor.

Sensor Model	SpO_2 Range 70% - 100%
OxiMax®	
MAX-A*, MAX-AL*	±2 digits
MAX-N*† (Adult)	±2 digits
MAX-N*† (Neonate)	±3 digits
MAX-P*	±2 digits
MAX-I*	±2 digits
MAX-R*‡	±3.5 digits
OxiCliq®	
OxiCliq A	±2.5 digits
OxiCliq P	±2.5 digits
OxiCliq N† (Adult)	±2.5 digits
OxiCliq N† (Neonate)	±3.5 digits
OxiCliq I	±2.5 digits
Reusable Sensor Models	
D-YS (Infant to Adult)	±3 digits
D-YS (Neonate)	±4 digits
D-YS with D-YSE	±3.5 digits
D-YS with D-YSPD	±3.5 digits
DS-100A	±3 digits
OXI-A/N (Adult)	±3 digits
OXI-A/N (Neonate)	±4 digits
OXI-P/I	±3 digits

* The accuracy specification under motion conditions is ±3. For a definition of motion, contact NELLCOR® Technical Services or your local representative.

† The MAX-N and the OxiCliq N were tested on patients >40 kg.

‡ The accuracy specification has been determined between saturations of 80%-100%.

Neonatal Sensor Accuracy

When sensors are used on neonatal subjects as recommended, the specified accuracy range is increased by ±1 digit, to account for the theoretical effect on oximeter measurements of fetal hemoglobin in neonatal blood. For example, MAX-N accuracy on neonates is ±3 digits, rather than ±2 digits.

Sensor Light Source

Wavelength	Infrared: 890 nm (nominal) Red: 660 nm (nominal)

Power Dissipation	Infrared: 22.5 mW (max) Red: 30 mW (max)

Factory Default Settings

SpO_2 (%)	HIGH Alarm Limit: 100
SpO_2 (%)	LOW Alarm Limit: 90
Response Mode	2 (for Mode 2: Fast Response)
SatSeconds™	0

NELLCOR® Patents

US Patent No. 4,802,486; 4,869,254; 4,928,692; 4,934,372; 5,078,136; 5,485,847; 5,743,263; 5,865,736; 6,035,223; 6,298,252; 6,463,310; 6,591,123; 6,675,031; 6,708,049; 6,801,797; Re. 35,122 and foreign equivalents.

Masimo SpO_2

Measurement Range

SpO_2	1 to 100%
Pulse Rate	25 to 240 beats/min
Perfusion Range	0.02 to 20%

Accuracy and Motion Tolerance

Saturation

Without Motion - Adult/Ped*	70 to 100% ±2 digits
Without Motion - Neonate*	70 to 100% ±3 digits
With Motion - Adult/Ped/Neo**†	70 to 100% ±3 digits
Low Perfusion‡	70 to 100% ±2 digits 0 to 69% unspecified

Pulse Rate

Without Motion	25 to 240 beats/min ±3 digits
With Motion	normal physiologic range 25 to 240 beats/min ±5 digits

* The Masimo SET® SpO_2 parameter with LNOP-Adt sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

**The Masimo SET® SpO_2 parameter with LNOP-Adt sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions at 2 to 4 Hz at an amplitude of 1 to 2 cm and a nonrepetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

†The Masimo SET® SpO_2 parameter with LNOP-Neo Pt sensors has been validated for neonatal motion accuracy in human blood studies on neonates while moving the neonate's foot at 2 to 4 cm against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus, one standard deviation.Plus or minus one standard deviation encompasses 68% of the population.

‡The Masimo SET® SpO_2 parameter has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 stimulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus, one standard deviation.Plus or minus one standard deviation encompasses 68% of the population.

Masimo® Sensor Accuracy

Sensor Model	SpO2 Range 70% - 100%
LNOP	
LNOP-ADT	± 2 digits
LNOP-ADT Long	± 2 digits
LNOP-PDT	± 2 digits
LNOP-NEO	± 3 digits
LNOP-NEO PT	± 3 digits
LNOP-DCI (reusable)	± 2 digits
LNOP-DCSC (reusable)	± 2 digits
LNOP-DCIP (reusable)	± 2 digits
NRI25 (reusable)	± 2 digits
LNOP-DC195 (reusable)	± 2 digits

Resolution

Saturation (% SpO_2)	1%
Pulse Rate (bpm)	1

Low Perfusion Performance

>0.02% Pulse Amplitude	Saturation (% SpO_2) ±2 digits
and % Transmission >5%	Pulse Rate ±3 digits

Interfering Substances

Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.

Sensor Light Source

Wavelength	Infrared: 905 nm (nominal) Red: 660 nm (nominal)
Power Dissipation	Infrared: 22.5 mW (max) Red: 27.5 mW (max)

Factory Default Settings

SpO_2 (%)	HIGH: 100
SpO_2 (%)	LOW: 90
Sensitivity Mode	2 (for low perfusion-Default)
Averaging Time	12 seconds
FastSAT Mode	0 (for Off)

Masimo Patents

5,482,036; 5,490,505; 5,632,272; 5,685,299; 5,758,644; 5,769,785; 6,002,952; 6,036,642; 6,067,462; 6,206,830; 6,157,850, and international equivalents.

Temperature

Scale	°Fahrenheit (F) °Celsius (C)
Range	
Predictive mode	Max: 41.1° C; 106.0° F Min: 35.6° C; 96.0° F
Monitor mode	Max: 41.1° C; 106.0° F Min: 26.7° C; 80.0° F
Monitor mode accuracy	± 0.1° C ± 0.2° F (when tested in a calibrated liquid bath; meets ASTM E1112, Table 1, in range specified)
Determination time	approx. 10 seconds, typical

Use only IVAC® probes and P850A probe covers. The size, shape, and thermal characteristics of the probe covers can affect the performance of the instrument. Inaccurate readings or retention problems may occur unless IVAC® probes and probe covers are used. Refer to Appendix D for reorder codes.

Factory Default Settings

Unit of measure	° F

IVAC® Patents

U.S. D300,728, D300,909

Pulse Rate

Factory Default Settings

Pulse Rate	HIGH: 150 LOW: 50

Refer to individual SpO_2 and BP sections.

B Appropriate Use of NIBP Simulators

For your notes

Appropriate Use of NIBP Simulators

NIBP Accuracy

Noninvasive Blood Pressure (NIBP) monitors are approved for sale in the U.S. by the FDA (1) and in Europe through the CE Mark. Both of these processes require that the accuracy of NIBP monitors be established through clinical testing - the use of NIBP simulators is not acceptable.

GE Healthcare has established accuracy using the AAMI SP-10 standard (2) and a similar standard exists in Europe (3). The AAMI standard specifies that the accuracy of NIBP monitors can be determined using either an invasive (intra-arterial) or noninvasive (auscultatory) blood pressure reference. Over the last 30 years, DINAMAP® accuracy has been established using an invasive central aortic blood pressure reference. More recently, the DINAMAP ProCare Monitor has also been validated against a manual auscultatory reference.

Clinical vs. Simulator Readings

There are a number of reasons why the clinical studies are required for the measurement of NIBP accuracy. Many physiologic measurements (e.g. ECG, HR, eTCO2) can be taken with little interaction between the monitor and the patient. These devices can typically be validated using previously recorded patient data.

Unlike the transducers/electrodes used in these devices, the NIBP cuff has two functions. In addition to sensing the pressure pulses in the cuff, the cuff occludes and then releases the patient's artery to create the conditions that allow blood pressure to be measured.

An "artificial arm" would need to test both the sensing and occluding functions of the cuff, and mimic the nonlinear dynamics of the artery to provide an effective clinical simulation. While this has been attempted (4), there are no effective "arms" available.

Commercial NIBP simulators do attempt to test either function of the NIBP cuff. Pressure signals are generated by the simulator in response to the inflation and deflation cycles of the monitor. While the cuff may be in the system, it is wrapped on a mandrel. The ability of the cuff to transducer pressure signals or to occlude the artery is not tested.

There are further limitations to the pressure pulses used by simulators. During the deflation of the cuff, the shape of the generated pressure oscillations changes as the cuff goes from systolic to diastolic pressures. This is due to the fact that the artery is only open when the arterial pressure is above cuff pressure. As can be seen in Figures 1A-1C, the shape of the oscillation changes as the cuff pressure changes, and the artery opens. Commercial NIBP simulators use one waveform shape at all pressure levels, which is simply scaled to reflect the oscillometric envelope.

In addition, the shape of the oscillation generated by commercial simulators does not match the shape of a typical oscillation measured during clinical testing (Figures 2A-2B). These differences in the shape of the pulses can effect how an NIBP monitor analyzes the oscillometric envelope. While it is possible to

develop an algorithm, which produces readings that correspond to the simulator settings, it is preferable to use the clinical data for algorithm development.

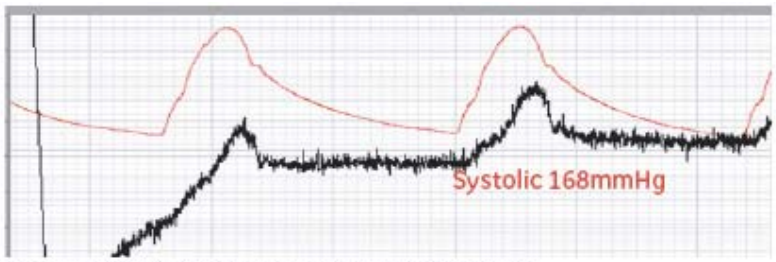


Figure 1A: Cuff Oscillation At Systolic Pressure
(— Invasive Pressure; — Cuff Pressure)

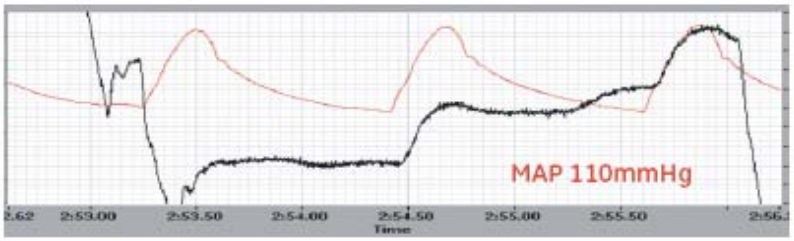


Figure 1B: Cuff Oscillation From A Clinical Measurement
(— Invasive Pressure; — Cuff Pressure)

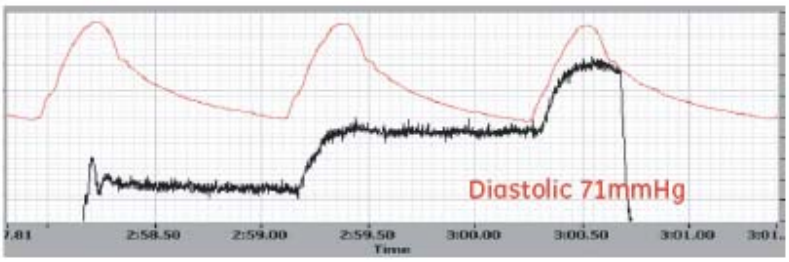


Figure 1C: Cuff Oscillation From A Clinical Measurement
(— Invasive Pressure; — Cuff Pressure)

What Do Simulator Manufactures Say?

The DNI Nevada (Fluke Biomedical) CuffLink manual states:

"Since the CuffLink produces the same response independent of the inflate/deflate cycle or the algorithm used by the monitor, we offer the term "Target Value" as an approximation of the patient's actual blood pressure" (5)

BioTek® BP Pump 2™ (Fluke Biomedical) manual, in response to the question of why monitor readings differ from the target values on the simulator, states:

"Neither the monitor or the BP Pump 2 is broken. Some monitors were designed to give readings close to those obtained by the Auscultatory method of blood pressure determinations. Other monitors have been designed to agree with Invasive blood pressure readings. It is well known that Invasive and Auscultatory BP readings on the same subject can be quite different" (6)

Both of these statements indicate that these simulators cannot be used to demonstrate the accuracy of an NIBP monitor.

Why Use Simulators?

Simulators provide a method for producing repeatable signals that can be used to check that the monitor is responding to noninvasive blood pressure signals. Reference values obtained from a particular make and model of an NIBP monitor can be used to confirm that no changes have occurred after service to that same type of monitor.

Simulators can also be used to test for leaks and conduct static pressure calibration of NIBP monitors and as part of preventive maintenance programs.

Summary

The accuracy of an NIBP monitor can only be determined by comparison to a clinical blood pressure reference. NIBP simulators are useful for certain types of testing, but should not be used for accuracy testing.

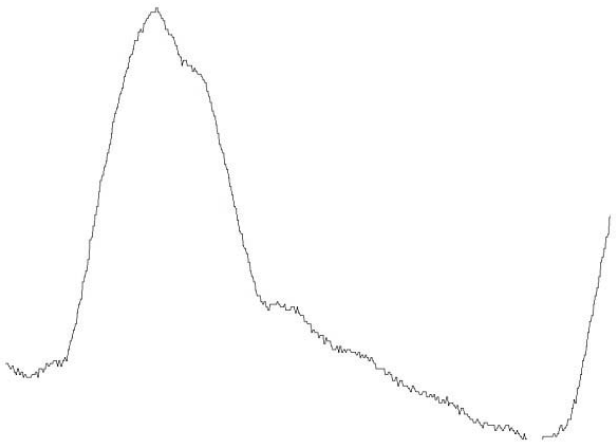


Figure 2A: Cuff Oscillation From A Clinical Measurement

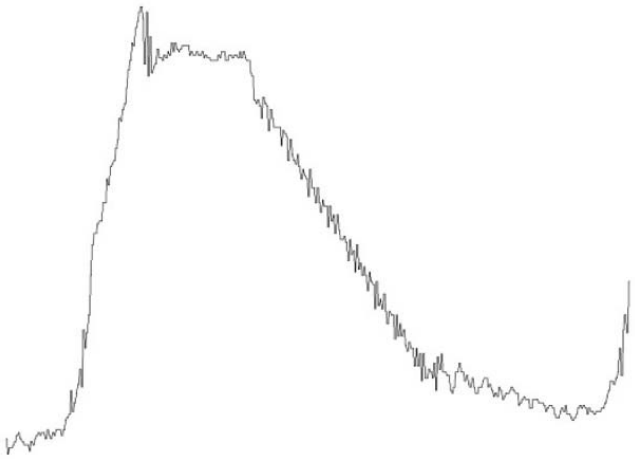


Figure 2B: Cuff Oscillation From A Simulator Measurement

References

1. FDA, CDRH, Non-Invasive Blood Pressure (NIBP) Monitor Guidance, March 10, 1997
2. ANSI/AAMI SP10:2002, Manual, Electronic or Automated Sphygmomanometers
3. EN 1060-4 2004 Specification for non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers
4. Mieke, S, Substitute of simulators for human subjects; Blood Press Monit, October 1, 1997; 2(5): 251-256
5. DNI Nevada CuffLink Non-Invasive Blood Pressure Analyzer, Operating and Service Manual; Revision E, 11/97
6. BP Pump 2 Noninvasive Blood Pressure Simulator and Tester, Operations Manual; Revision C, January 2003

Bio-Tek and BP Pump 2 are trademarks of Bio-Tek Instruments.

C Electromagnetic Compatibility (EMC)

For your notes

Electromagnetic Compatibility (EMC): *ProCare* Monitor

Changes or modifications to this system not expressly approved by GE Medical Systems can cause EMC issues with this or other equipment. This system is designed and tested to comply with applicable regulation regarding EMC and must be installed and put into service according to the EMC information stated in this appendix.

CAUTION
Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

The equipment or system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The DINAMAP® *ProCare* Monitor is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to assure that the DINAMAP® *ProCare* Monitor is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions EN 55011	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions EN 55011	Class B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The DINAMAP® *ProCare* Monitor is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to assure that the DINAMAP® *ProCare* Monitor is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for input/output lines	± 2 kV for power supply lines ±1 kV for input/ output lines	Mains power should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_t (>95% dip in U_t) for 0.5 cycles <40% U_t (>60% dip in U_t) for 5 cycles <70% U_t (>30% dip in U_t) for 25 cycles <5% U_t (>95% dip in U_t) for 5 s	<5% U_t (>95% dip in U_t) for 0.5 cycles <40% U_t (>60% dip in U_t) for 5 cycles <70% U_t (>30% dip in U_t) for 25 cycles <5% U_t (>95% dip in U_t) for 5 s	Mains power should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power Frequency (50/ 60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

NOTE:

U_t is the AC mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	3 V rms	Portable and mobile RF communications equipment should not be used closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by reflection from structures, objects, and people.

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment.

[b]Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

The table below provides the recommended separation distances (in meters) between portable and mobile RF communications equipment and the DINAMAP® *ProCare* Monitor.

The DINAMAP® *ProCare* Monitor is intended for use in the electromagnetic environment on which radiated RF disturbances are controlled. The customer or the user of the DINAMAP® *ProCare* Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DINAMAP® *ProCare* Monitor as recommended below, according to the maximum output power of the communications equipment.

	Separation Distance in Meters (m) According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter in Watts	**150 kHz to 80 MHz** [a] $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** [a] $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** [a] $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
[a]At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			

For transmitters rated at a maximum output power not listed above, the recommended separation distance [*d*] in meters (m) can be estimated using the equitation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE:

These guidelines may not apply in all instances. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Compliant Cables and Accessories

CAUTION
The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.

The table below lists cables, transducers, and other applicable accessories with which GE Medical Systems claims EMC compliance.

NOTE: Any supplied accessories that do not affect EMC compliance are not included.

Part No	Description	Maximum Lengths
Temperature Cables and Probes		
2008774-001	Turbo-Temp Oral Probe, Blue	3.0 m / 10 ft
2008775-001	Turbo-Temp Rectal Probe, Red	3.6 m / 12 ft
2016998-001	Dual Temp Cable	20 cm / 8 in
Pulse Oximetry Cables and Sensors		
407705-006	Nellcor DuraSensor Reusable Finger Probe (DS100A)	0.9 m/ 3 ft
2008773-001	Nellcor Interface Cable, OxiSmart, DOC 10 Cable	3.3 m / 11 ft
2009743-001	Masimo PC08 Cable	2.5 m / 8.2 ft
2009745-001	Masimo Finger Sensor, Adult, Reusable	N/A
Accessories		
316579-001	AC Cable, Hospital Grade, AHA	3.6 m / 12 ft
2013057-001	Universal AC/DC Adapter	N/A
ILC-1926	Isolated Level Converter	N/A

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